

EU RAPID ALERT PLATFORM

**Multi-Country Workshop on Increasing Blood
Availability and Providing the Highest Donor and
Patient Safety in Transfusion Therapy in
Emergency Special Circumstances _7-9 July
2014**

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QUICK ALERTS

Why quick alerts?

- ◆ Article 9 of Directive 2005/61/EC: *“Member States shall ensure that their competent authorities communicate to each other such information as is appropriate with regard to serious adverse reactions and events in order to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded.*
- ◆ Annex II Dir 2004/33/EC: Communicable diseases
 - Annex 2.3 Dir 2004/33/EC: Notification of deferrals to the Commission *« with a view to Community action »*
- ◆ Scope of the quick alerts:
 - Product defects
 - Threats to health/blood donations
- ◆ Approach developed for tissues and cells too

QUICK ALERTS BLOOD

Ex. of quick alerts

- ◆ *Chikungunya*
- ◆ *West Nile Virus*
- ◆ *Dengue*
- ◆ *Q fever*
- ◆ *Trima Accel Automated Blood Collection System*
- ◆ *Ortho Biovue System Cassettes*
- ◆ *Macopharma Blood Bags*
- ◆ *RadSure (irradiation indicator)*

QUICK ALERTS

Questions to address

- ◆ Protocol for triggering/dissemination?
 - Quick alerts vs. Information sharing
 - Information exchange channels

- ◆ Preventive measures?
 - In the country directly concerned
 - In the countries potentially threatened
 - Epidemiological/risk assessment

- ◆ Follow up?
 - Closure of the alerts
 - Preparation for likely outbreaks

QUICK ALERTS

Development steps

- ◆ 2006-2010: Communication by e-mail (mailinglist of representatives of NCAs and MS)
- ◆ 2010-2012: CIRCA-CAs and CIRCA-QuickAlerts Blood: sharing all documents in relation of meetings of CAs and other relevant informations, and managing the quick alerts
- ◆ Since January 2013: CIRCA-BC (Communication and Information Resource Centre for Administrations, Businesses and Citizens).
- ◆ Since February 2014: RAB: Rapid Alerts platform for blood

RAPID ALERTS PLATFORM

AGENDA

1. Introduction
2. RAB presentation – Version 1.0
3. RAB data protection
4. RAB Support
5. RAB Standard Operating Procedures
6. Hands-on
7. Next steps

INTRODUCTION (1)

The scope of the Rapid Alert system for human blood and blood components (RAB) is to provide the competent authorities of the European Union (EU) and European Economic Area (EEA) countries and the European Commission with **an effective and secure network tool for the exchange of information on urgent measures, to ensure the safety of human blood and blood components for transfusion.**

This rapid exchange of information allows all the Member States to verify immediately whether they are affected by a problem initially raised and for which a precautionary/corrective measure should be implemented.

The system includes:

- An "administration" module available for restricted list of users within the official list of Competent Authorities (CA) and members of the European Commission (EC) in order to create, follow-up and consult alerts and final reports on tissues and cells.
- An alert form and notification process
- A set of notifications/reminders (based on deadlines and specific events)
- A search functionality
- An easy to use and user friendly interface

INTRODUCTION (2)

Article 9 of the Directive 2005/61/EC regarding communication of information between competent authorities and to the Commission provides for the Member States to

"ensure that their competent authorities communicate to each other such information as is appropriate with regard to serious adverse reactions and events in order to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded."

This procedure does NOT replace the existing national procedures by competent authorities of Member States for communicating the information to the relevant parties in their own national healthcare system.

This procedure is NOT applicable for human or veterinary medicinal products, human tissues and cells, organs or medical devices.

However, where precautionary/corrective actions taken are relevant for these other sectors, an exchange of information should be ensured with the national and European regulatory authorities responsible for these sectors.

RAB PRESNETATION – V1.0

1. Key stakeholders and user roles
2. Registration process
3. Alerts workflow
4. Main system features – Alert and Final Report
5. Notifications/reminders

KEY STAKEHOLDERS

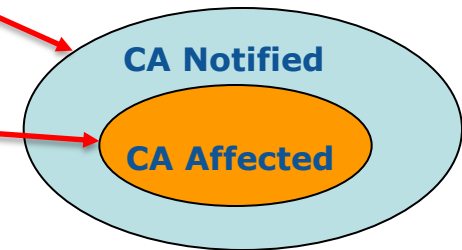
- Main stakeholders
 - ❖ **CA** (Competent authorities) [28 Member States, +/- 50 Competent Authorities]
 - ❖ **EC** (Unit D4 - Substances of human origin and Tobacco control)
- Other stakeholders
 - ❖ European Medicine Agency
 - ❖ European Centre for Disease Control
 - ❖ EWRS contact points
 - ❖ EC - other SANCO units:
 - - B2 Medical devices
 - - C3 Health threats
 - - D6 Pharmaceuticals
 - ❖ World Health Organisation
 - ❖ Other SoHO Network (Tissues & Cells, Organs)



All the **other stakeholders** will have only a **read access**. Some information like CA initiator person detail, ... will not be visible.

USER ROLES

1. CA (Competent authorities)
 1. CA initiator
 1. Create new alert
 2. Update the alert content
 3. Notify other CA and other stakeholders
 4. Choose the reporter CA (in the list of notified CA) who will write the final report
 2. CA notified
 1. Comments an alert for which it has been notified
 2. Forward the alert to another not yet notified CA
 3. Approve or reject the final report
 - CA 'affected'
 1. Comment the final report
 3. CA reporter (supervisor)
 1. Complete the final report
 2. Submit the final report for comment to all the affected CA
 3. Close the alert
2. EC (European Commission) - Administrator role
 1. Validation of the user access
 2. Management of the reference list / Library
 3. Follow-up of dedicated functional mailbox
 4. Create an alert (as Initiator)



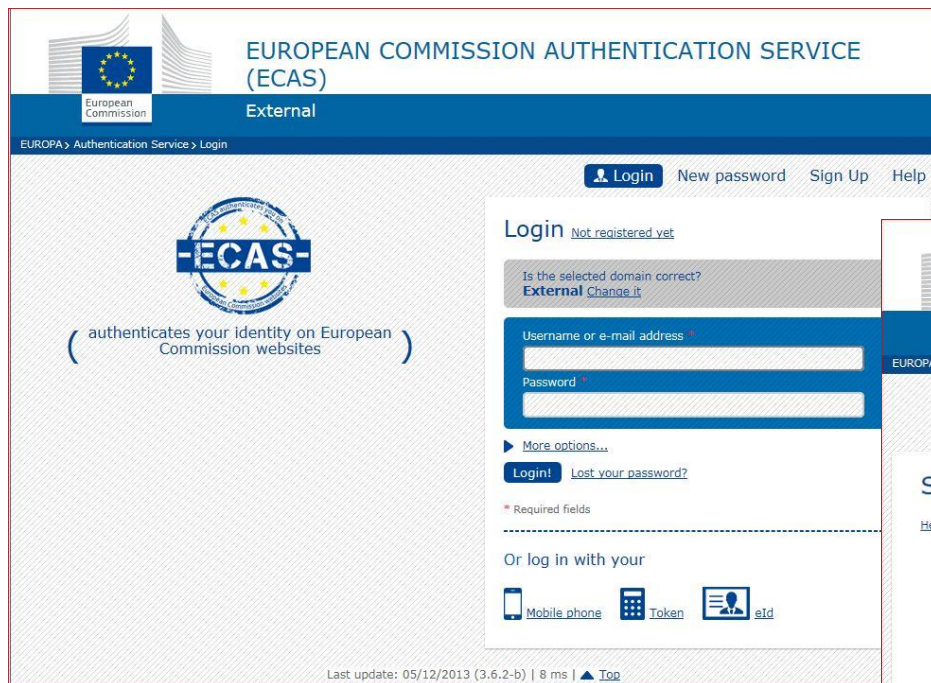
REGISTRATION PROCESS

- **Via the official authentication system used by European Commission (ECAS) and getting authorisation via SAAS.**
- **Same login/password**
 - 1.if member of several networks linked to ECAS
 - 2.for CIRCA BC
- **Before to access the RAB system the user will have to register via this system.**
- **First validation of the access will be done by EC.**
- **A local administrator can validate accesses for his/her organisation colleagues.**
- **Other stakeholders' access will be managed by the EC-SANCO-SoHO team**

ECAS: CREATE A PERSONAL ACCOUNT (1)

- ◆ **ECAS: European Commission Authentication Service**
- ◆ This system provides the user with a login and password to connect to multiple European Commission applications.
- ◆ **Remark:** Please do not create generic accounts.
- ◆ **URL:** <https://webgate.ec.europa.eu/cas/login>

ECAS: CREATE A PERSONAL ACCOUNT (2)



EUROPEAN COMMISSION AUTHENTICATION SERVICE (ECAS)
External

EUROPA > Authentication Service > Login

[Login](#) [New password](#) [Sign Up](#) [Help](#)

Login [Not registered yet](#)

Is the selected domain correct?
External [Change it](#)

Username or e-mail address *

Password *

[More options...](#)

[Login!](#) [Lost your password?](#)

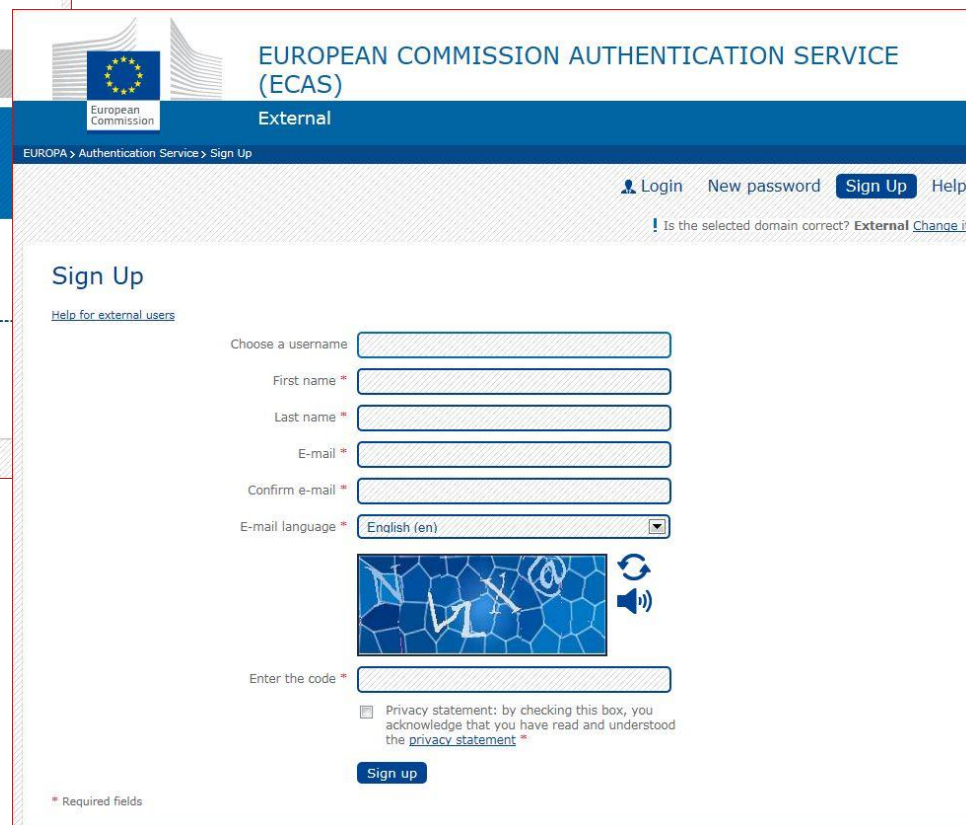
* Required fields

Or log in with your

[Mobile phone](#) [Token](#) [eID](#)

Last update: 05/12/2013 (3.6.2-b) | 8 ms | [Top](#)

(authenticates your identity on European Commission websites)



EUROPEAN COMMISSION AUTHENTICATION SERVICE (ECAS)
External

EUROPA > Authentication Service > Sign Up

[Login](#) [New password](#) [Sign Up](#) [Help](#)

! Is the selected domain correct? **External** [Change it](#)

Sign Up

[Help for external users](#)

Choose a username *


First name *

Last name *

E-mail *

Confirm e-mail *

E-mail language * **English (en)**

 [Refresh](#) [Volume](#)

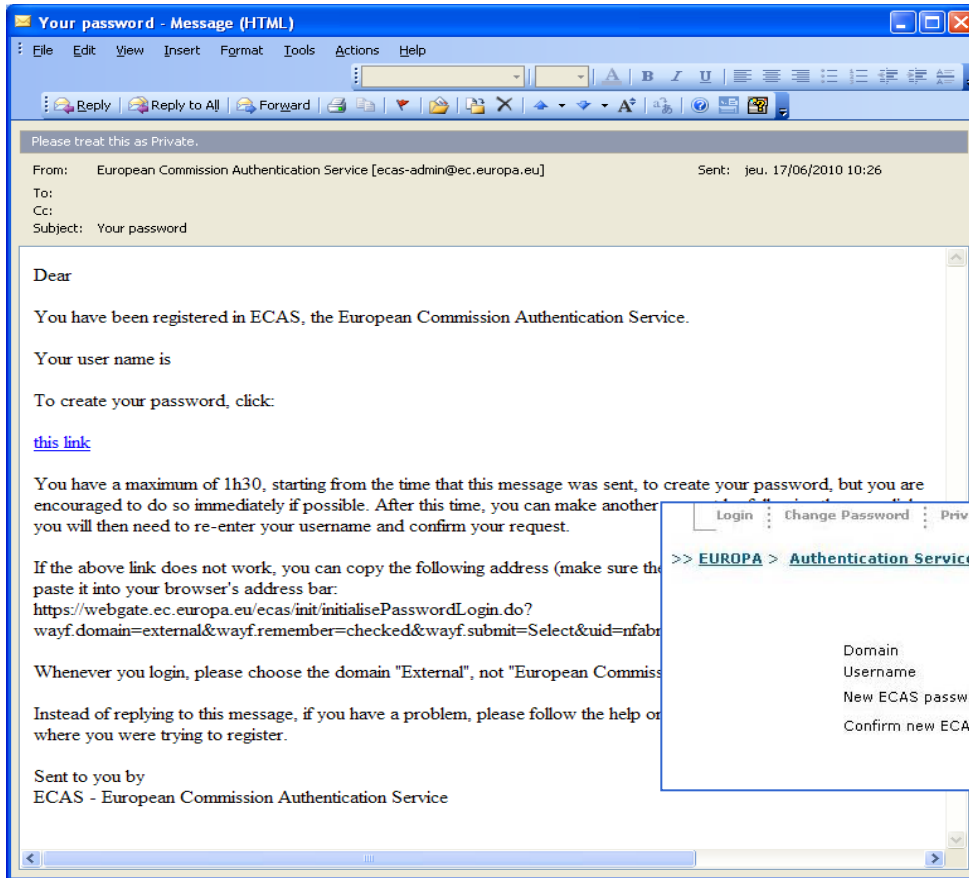
Enter the code *

Privacy statement: by checking this box, you acknowledge that you have read and understood the [privacy statement](#) *

[Sign up](#)

* Required fields

ECAS: CREATE A PERSONAL ACCOUNT (3)



The screenshot shows a web page titled "Create your new password and login". The page has a navigation menu with "Login", "Change Password", "Privacy Statement", "Contact", and "Help". The breadcrumb trail is ">> EUROPA > Authentication Service > Password initialisation".

The main heading is "Create your new password and login".

There are two radio buttons for "Domain": "External" (selected) and "European Commission".

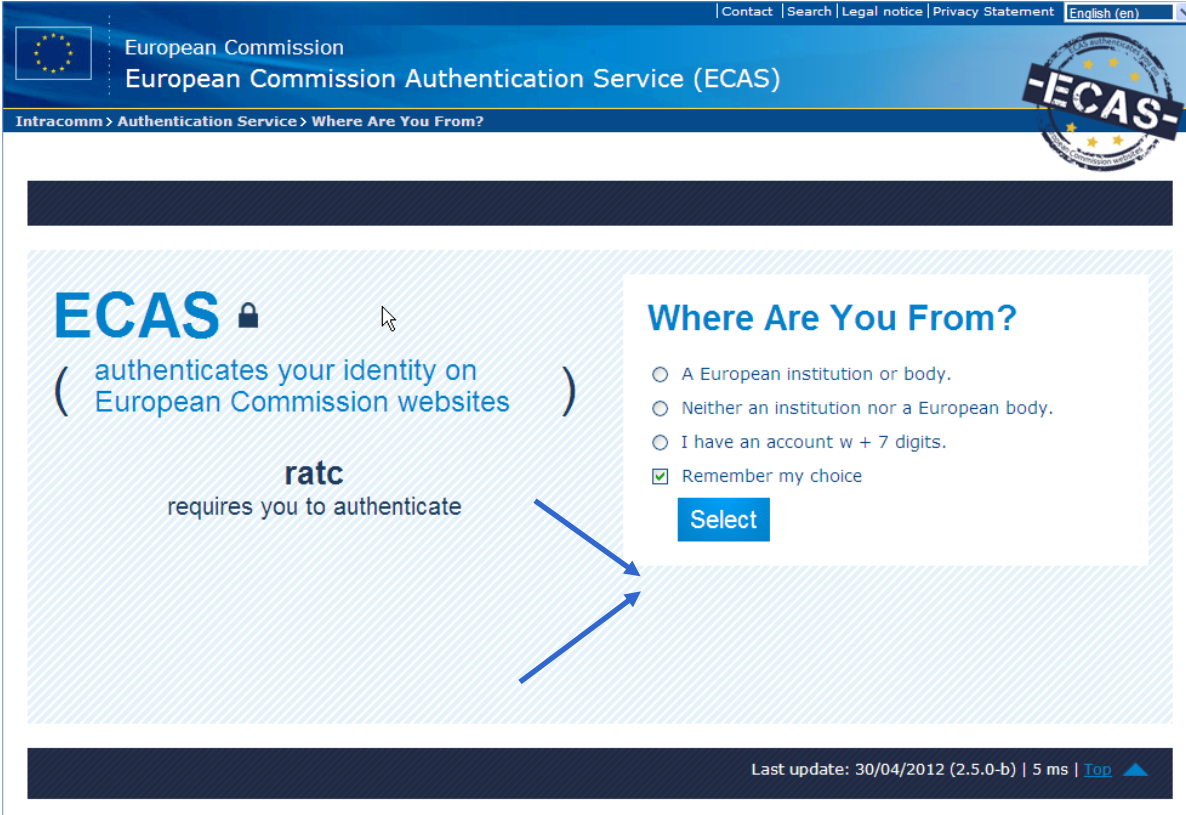
There are two input fields for "New ECAS password" and "Confirm new ECAS password".

A "Submit" button is located below the input fields.

On the right side, there is a note: "This page allows you to reset your ECAS password after your original request. This password should only be used when prompted, as ECAS is identified by a distinctive logo and your connection (padlock for Internet Explorer). New"

ECAS: FIRST LOGIN (1)


- ◆ URL: <https://webgate.ec.europa.eu/ratc>



The screenshot shows the ECAS login interface. At the top, there is a blue header with the European Commission logo and the text "European Commission Authentication Service (ECAS)". Below this, a navigation bar contains "Intracomm > Authentication Service > Where Are You From?". The main content area is divided into two sections. On the left, the text reads "ECAS (authenticates your identity on European Commission websites)" and "ratc requires you to authenticate". On the right, a white box titled "Where Are You From?" contains three radio button options: "A European institution or body.", "Neither an institution nor a European body.", and "I have an account w + 7 digits.". A checked checkbox labeled "Remember my choice" is also present, along with a blue "Select" button. Two blue arrows point from the text "requires you to authenticate" to the "Select" button. The footer of the page indicates "Last update: 30/04/2012 (2.5.0-b) | 5 ms | Top ▲".

ECAS: FIRST LOGIN (2)

The screenshot displays the ECAS (European Commission Authentication Service) interface. At the top, there is a navigation bar with links for 'Contact', 'Search', 'Legal notice', 'Privacy Statement', and a language dropdown set to 'English (en)'. Below this, the text 'External European Commission Authentication Service (ECAS)' is visible, along with a circular logo featuring the ECAS acronym and the European Union flag. The main content area is titled 'RATC' and shows an 'Access denied' message. A sidebar on the left provides information about ECAS and the RATC application.

ECAS 
(authenticates your identity on European Commission websites)

ratc
requires you to authenticate

Access denied
You are not authorized to access this page.
You are not authorized to access this application RATC. Please follow this [link](#) to submit an access request form.

Legal notice
The system you are trying to access is the property of the European Commission and is provided solely for use by those which have been granted explicit authorization for it. If you are not yet a user of the system but would like to request access to it, you should contact the system administrator following the provided link. Your attention is drawn to the legal consequences that any false, fictitious, or fraudulent statement or representation made by you when submitting an access request for this system may entail.

Sanco

SAAS: REQUEST AN ACCESS TO RAB (1)

- ◆ **SAAS: SANCO Authentication and Authorisation System**
- ◆ This system provides the user with a profile and access rights for a specific European Commission application, in this case the RAB.
- ◆ **Remark:** SAAS provides also administration interfaces to the Local Admin.
- ◆ **URL:** <https://webgate.ec.europa.eu/saas>

SAAS: REQUEST AN ACCESS TO RAB (2)

The screenshot shows the 'Saas - Authorization System' interface. At the top, there is a navigation bar with links for 'Disclaimer', 'Support', 'Paolo CATALANI', and 'Logout', along with a language dropdown set to 'English (en)'. The main header features the European Commission logo and the text 'Saas - Authorization System' and 'Rapid Alert for Tissues and Cells'. Below this is a breadcrumb trail: 'European Commission > DG Health & Consumers > Saas'. A secondary navigation bar includes 'My requests', 'Manage as', and a green 'Request access' button. A light blue box contains a privacy notice: 'The Commission shall process personal data information pursuant to Regulation 45/2001 EC on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.' The main section is titled 'New application access' and contains a four-step progress indicator: 1. Select application (highlighted), 2. Select organisation, 3. Select access profile, and 4. Recap and Submission. Below the progress indicator is a form with a label 'Application' and a dropdown menu currently showing 'Rapid Alert for Tissues and Cells'. A blue arrow points from a box labeled 'Select the application:' to the dropdown menu. A green button at the bottom right of the form reads 'Next step, step 2 : select an existing organisation →'. The footer of the page contains the text 'EC DG SANCO (v2.0.3) | Top | catalpa (catalpa)'.

SAAS: REQUEST AN ACCESS TO RAB (3)

New application access

1 Select application

2 Select organisation

3 Select access profile

4 Recap and Submission

Please choose your Department:

Internal Organisation

SANCO.DDG1.D.4

Or one of the Organisations below:

* Organisations

25 records per page

Search:

Select your organisation:

Name ▲

- / Blood network
- / Blood network / Belgium - Federal Agency for Medicinal products and Health products
- / Blood network / France - Agence Nationale de Sécurité du Médicament (ANSM)
- / Blood network / Greece - National Blood Centre - Ministry of Health
- / Blood network / Haemovigilance WG
- / Blood network / Irish Medicines Board (IMB)
- / Blood network / Italian National Blood Center

SAAS: REQUEST AN ACCESS TO RAB (4)

The screenshot displays the 'Saas - Authorization System' interface. At the top, there is a header with the European Commission logo and the text 'Saas - Authorization System' and 'Rapid Alert for Tissues and Cells'. Below this is a navigation bar with 'European Commission > DG Health & Consumers > Saas'. A secondary navigation bar contains 'My requests', 'Manage as', and a 'Request access' button. A light blue box contains the text: 'The Commission shall process personal data information pursuant to Regulation 45/2001 EC on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.'

New application access

Progress indicators show four steps: 1. Select application, 2. Select organisation, 3. Select access profile (highlighted in orange), and 4. Recap and Submission.

***Access Profile**

- Competent Authority
- Other bodies

A blue box with the text 'Select your profile:' has a blue arrow pointing to the 'Other bodies' radio button.

Next step, step 4 : type a comment →

EC DG SANCO (v2.0.3) | Top | catalpa (catalpa)

SAAS: REQUEST AN ACCESS TO RAB (5)

New application access

1 Select application 2 Select organisation 3 Select access profile 4 Recap and Submission

Recap

Application Rapid Alert for Tissues and Cells

Organisation / Blood network / Belgium - Federal Agency for Medicinal products and Health products (Already existing)

Access Profile Competent Authority

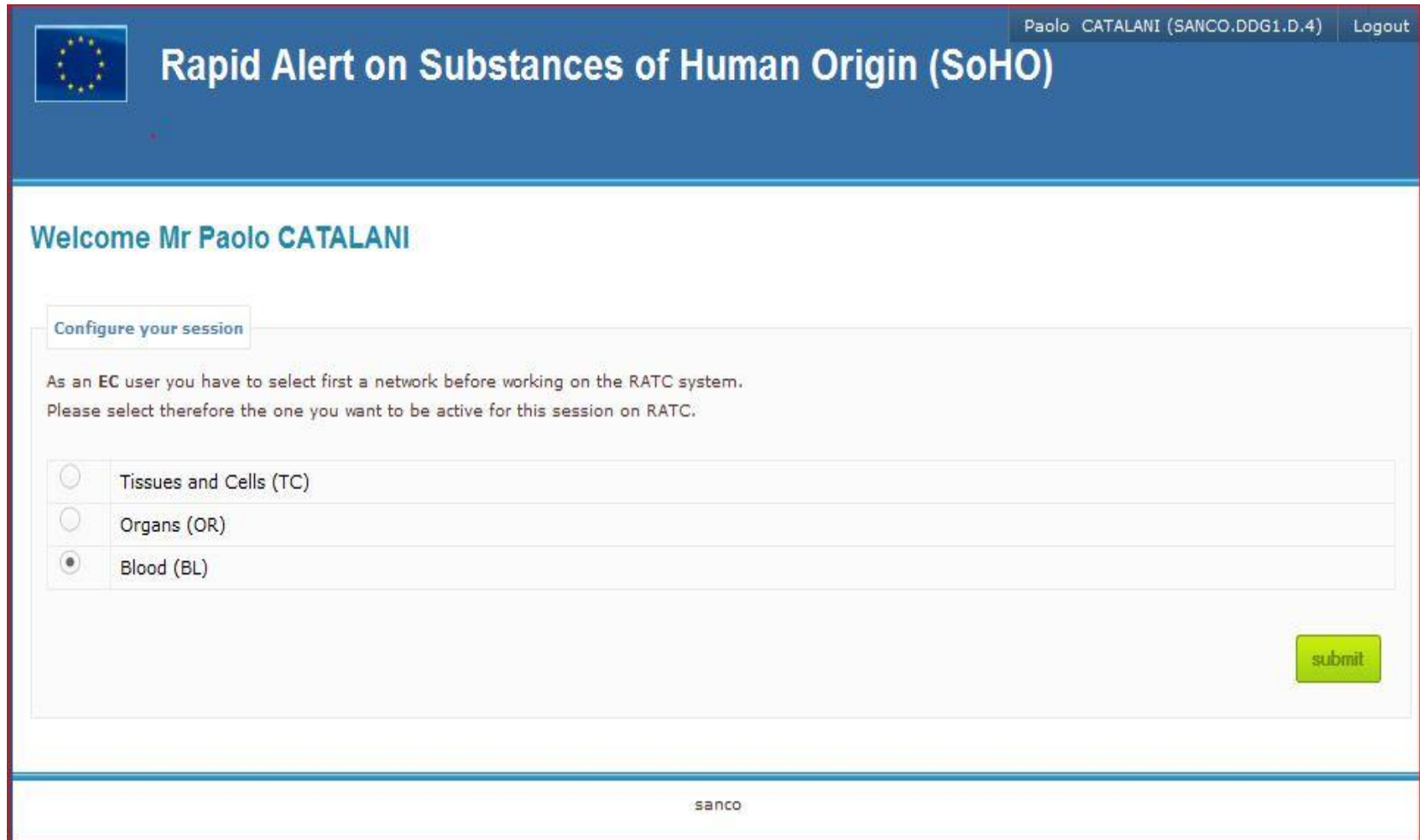
Comments

Click on this button to validate your choice.

Before submitting
A request to get access to an application will be validated by the administrators, this is a **manual process** and can take a few days.

Back **Submit request access**

RAPID ALERT ON SOHO - PLATFORM



The screenshot shows a web interface for the 'Rapid Alert on Substances of Human Origin (SoHO)' platform. At the top right, the user is identified as 'Paolo CATALANI (SANCO.DDG1.D.4)' with a 'Logout' link. The main header features the European Union flag and the title 'Rapid Alert on Substances of Human Origin (SoHO)'. Below the header, a welcome message reads 'Welcome Mr Paolo CATALANI'. A section titled 'Configure your session' contains instructions: 'As an EC user you have to select first a network before working on the RATC system. Please select therefore the one you want to be active for this session on RATC.' Three radio button options are listed: 'Tissues and Cells (TC)', 'Organs (OR)', and 'Blood (BL)'. The 'Blood (BL)' option is selected. A green 'submit' button is located at the bottom right of the configuration area. The footer of the page displays the 'sanco' logo.

Paolo CATALANI (SANCO.DDG1.D.4) Logout

Rapid Alert on Substances of Human Origin (SoHO)

Welcome Mr Paolo CATALANI

Configure your session

As an EC user you have to select first a network before working on the RATC system.
Please select therefore the one you want to be active for this session on RATC.

Tissues and Cells (TC)

Organs (OR)

Blood (BL)

submit

sanco

SYSTEM OVERVIEW: DASHBOARD

Paolo CATALANI (SANCO.DDG1.D.4) Profile Change network Logout

Rapid Alert on Substances of Human Origin (SoHO) - Blood

Dashboard Alerts Documents Library Administration Useful links

Dashboard Create alert

Alert list My alerts My final reports

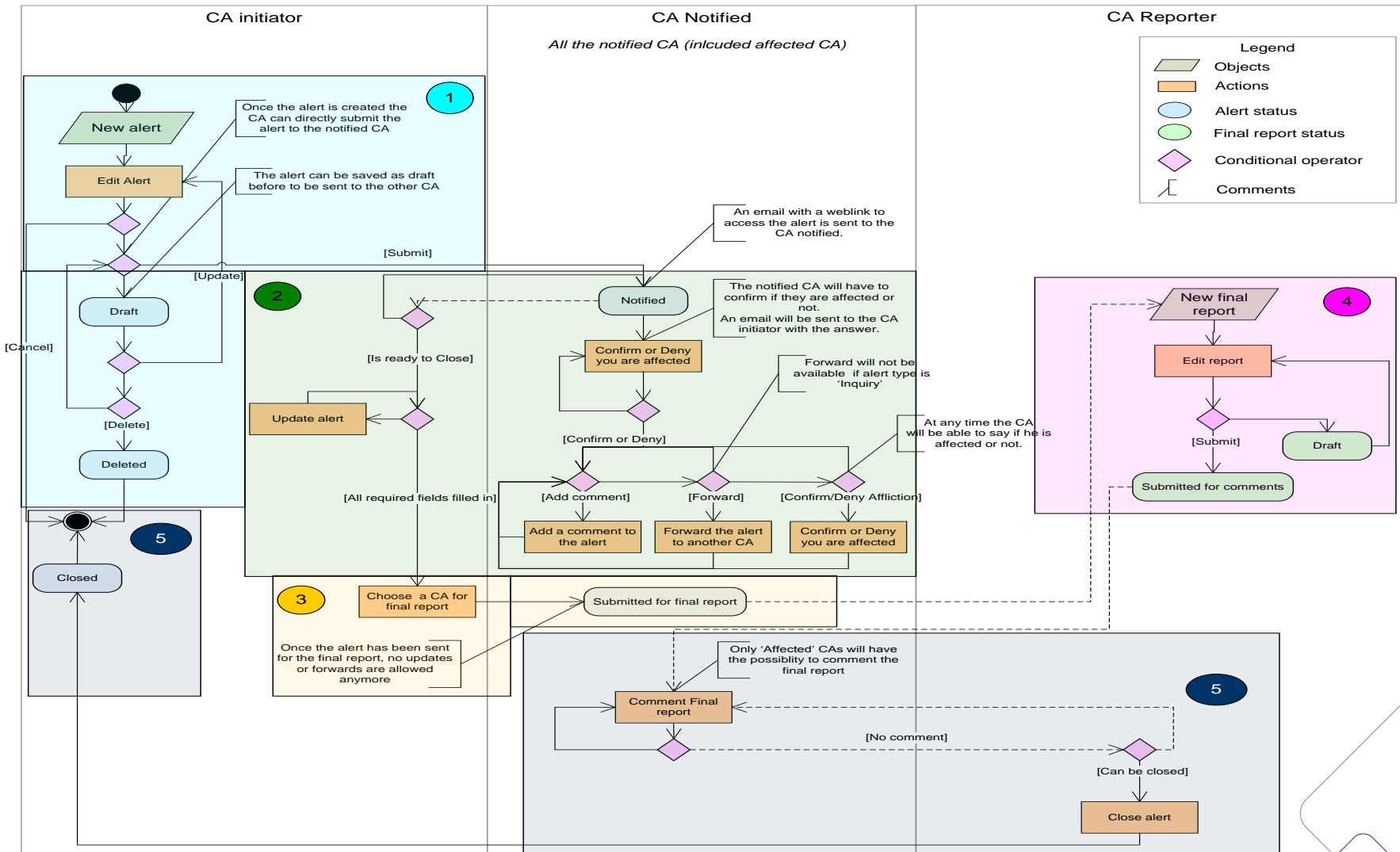
Show 10 entries Filter:

Alert reference	Notification Date	Component	Initiator CA	Notified CAs	Status of alert	Status of final report	
BE-2013-16	16/12/2013	Platelets	BE	BE, FR, GR, IE, IT	Submitted	N/A	
BE-2013-10	10/12/2013	Whole blood	BE	FR	Submitted	N/A	
BE-2013-12	10/12/2013	Whole blood	BE	FR	Submitted	N/A	
BE-2013-9	09/12/2013	Red blood cell	BE	FR, GR, IT	Submitted	N/A	
BE-2013-3	05/11/2013	Platelets	BE	BE, FR, GR, IE, IT	Submitted	N/A	
EC-2013-13	05/11/2013	Red blood cell	BE	BE, FR, GR, IE, IT	Submitted	N/A	
IT-2013-5	05/11/2013	Plasma	IT	BE, FR	Submitted	N/A	
BE-2013-17	19/12/2013	More than one blood component	BE	AT, BG, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK	Prepared for closure	Waiting for comment	
BE-2013-15	11/12/2013	More than one blood component	BE	FR	Prepared for closure	Waiting for comment	
BE-2013-11	10/12/2013	Whole blood	BE	FR, IE, IT	Prepared for closure	Waiting for comment	

Showing 1 to 10 of 13 entries

First Previous 1 2 Next Last

ALERTS WORKFLOW



MAIN SYSTEM FEATURES - ALERT

- **Registration**

- **Alert**

- 1 { » **Create a new alert**
- 2 { » **Notify the CA**
- » **Update an alert**
- » **Add comments to the alert**
- » **Confirm or deny affected by the alert**
- » **Forward the alert to another CA**
- 5 { » **Closure of the alert**

MAIN SYSTEM FEATURES – FINAL REPORT

- **Final report**

4

- » **Complete final report**

3

- » **Selection of the CA reporter**

5

- » **Comments by 'Affected' CA**

- **Notifications / Reminders (by email)**

- **Search function**

- **Document Library**

SYSTEM OVERVIEW: NEW ALERT SCREEN (1)

Type of alert:

- Quality and safety
- Information notice
- Epidemiological alert
- Inquiry (only between two Member States)
- Other

Component concerned:

- Plasma
- Platelets
- Whole Blood
- Red Blood Cells
- More than one blood component
- All blood components

Paolo CATALANI (SANCO.DDG1.D.4) Profile Change network Logout

Rapid Alert on Substances of Human Origin (SoHO) - Blood

Dashboard Alerts Documents Library Administration Useful links

New Alert

Alert details Problem details Technical Details

Alert details

Reference EC-2014-DRAFT(324)
Creation date 08/01/2014

* Type of alert

* Component concerned

* Treatment/Specification

Proposed	Selected
<input type="button" value="Add all"/>	<input type="button" value="Remove all"/> 0 items selected

SYSTEM OVERVIEW: NEW ALERT SCREEN (2)

Treatment/Specification:

- Apheresis
- Autologous
- Buffy coat removed
- Cryoprecipitate
- Cryoprecipitate-depleted
- Fresh-frozen plasma
- Frozen/cryopreserved
- Granulocytes
- In additive solution
- Irradiated
- Leucocyte-depleted
- No additional specifications
- Pathogen inactivated
- Pooled
- Recovered
- Single unit
- Thawed
- Washed

Paolo CATALANI (SANCO.DDG1.D.4) Profile Change network Logout

Rapid Alert on Substances of Human Origin (SoHO) - Blood

Dashboard Alerts Documents Library Administration Useful links

New Alert

Alert details Problem details Technical Details

Alert details

Reference EC-2014-DRAFT(324)

Creation date 08/01/2014

* Type of alert

* Component concerned

* Treatment/Specification

Proposed	Selected
<input type="button" value="Add all"/>	<input type="button" value="Remove all"/> 0 items selected

SYSTEM OVERVIEW: ALERT SCREEN (3)

Initiator Competent Authority

<p>Initiator CA Contact person</p> <p>EC Paolo CATALANI (SANCO.DDG1.D.4)</p>	<p>Network Contact person details</p> <p>Blood Email: Paolo.CATALANI@ec.europa.eu Phone: 81896</p>
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Notified Competent Authorities

* **Notified CA**

<input type="checkbox"/> All	<input type="checkbox"/> AT	<input type="checkbox"/> BE	<input type="checkbox"/> BG	<input type="checkbox"/> CY	<input checked="" type="checkbox"/> CZ
<input type="checkbox"/> DE	<input checked="" type="checkbox"/> DK	<input type="checkbox"/> EE	<input type="checkbox"/> ES	<input type="checkbox"/> FI	<input type="checkbox"/> FR
<input type="checkbox"/> GB	<input type="checkbox"/> GR	<input type="checkbox"/> HR	<input type="checkbox"/> HU	<input checked="" type="checkbox"/> IE	<input type="checkbox"/> IT
<input type="checkbox"/> LI	<input type="checkbox"/> LT	<input type="checkbox"/> LU	<input type="checkbox"/> LV	<input type="checkbox"/> MT	<input type="checkbox"/> NL
<input type="checkbox"/> NO	<input type="checkbox"/> PL	<input checked="" type="checkbox"/> PT	<input type="checkbox"/> RO	<input type="checkbox"/> SE	<input type="checkbox"/> SI
<input type="checkbox"/> SK					

Proposed CAs

Add all
CZ - Czech Republic - State Institute for Drug Control +

Selected CAs

Remove all	4 items selected
CZ - Czech Republic - Ministry of Health --	
DK - Danish Health and Medicines Authority --	
IE - Irish Medicines Board (IMB) --	
PT - Portugal - Authority for Blood and Transplantation... --	

It is relevant for:

<input type="checkbox"/> Network CAs Tissues and Cells	<input type="checkbox"/> Epidemiological sector (ECDC/EWRS)
<input checked="" type="checkbox"/> Medical devices (SANCO)	<input type="checkbox"/> Network CAs Organs
<input type="checkbox"/> Pharmaceutical sector (EMA)	

If one or more of these boxes are ticked, the initiator of this alert must inform the relevant national competent authority(ies) in his/her Member State responsible for that/those sector(s). (Please refer to section 4.4 of the SOP for further information)

SYSTEM OVERVIEW: NEW ALERT SCREEN (4)

Prescribe activities:

- Collection
- Testing
- Processing
- Storage
- Distribution
- Transport
- Other

Alert details | Problem details | Technical Details

Prescribe activities

Proposed	Selected
Add all	Remove all 0 items selected
Collection +	
Distribution +	
Other +	
Processing +	
Storage +	
Testing +	
Transport +	

Problem details

* Problem/Nature of the alert

Action taken or planned

None Recall Discarded
 Liaison with other sector Look back Quarantine
 Other

Recommendation

! Attached documents

! Attachments are limited to 5 documents of a maximum total size of 2mb. Accepted file types are : PDF, JPG or JPEG.

Name	Option
------	--------

Add Documents

SYSTEM OVERVIEW: NEW ALERT SCREEN (5)

Paolo CATALANI (SANCO.DDG1.D.4) Profile Change network Logout

Rapid Alert on Substances of Human Origin (SoHO) - Blood

Dashboard Alerts Documents Library Administration Useful links

New Alert

Alert details Problem details Technical Details

Sector concerned MD IVD Pharma Epidemiological

Process


Product

Batch number

Other information

Save as draft Send alert Cancel

SYSTEM OVERVIEW: ALERT SUMMARY



Paolo CATALANI (SANCO.DDG1.D.4) Profile Change network Logout

Rapid Alert on Substances of Human Origin (SoHO) - Blood

Dashboard Alerts Documents Library Administration Useful links

View alert

Reference: IT-2013-5 **Creation date:** 05/11/2013 12:39:42 **Submission date:** 05/11/2013 12:41:25
Component concerned: Plasma **Type of alert:** Information notice **Alert status:** Submitted

Alert details Problem details Comments Notified CA's History

Involved Competent Authorities

Initiator CA Italian National Blood Centre
Network Blood
Contact person Giuseppina FACCO **Contact person details** Email: emovigilanza.cns@iss.it
Phone:

Treatment/Specification: Cryoprecipitate-depleted

Notified CAs BE, FR
Affected Cas
Is relevant for: Network CAs Organs


Technical Details

Sector concerned IVD
Pharma
Epidemiological

Process retr
Product ter
Batch number tre
Other information tre

Print alert Forward alert Add Comment Back

SYSTEM OVERVIEW: FINAL REPORT DETAILS



Paolo CATALANI (SANCO.DDG1.D.4) Profile Change network Logout

Rapid Alert on Substances of Human Origin (SoHO) - Blood

Dashboard Alerts Documents Library Administration Useful links

View Final report for EC-2013-11

Start date: 11/10/2013 09:44:07 **Submission date:** 11/10/2013 09:46:25 **End date:** 11/10/2013 09:46:44
CA in charge of the report: SANCO.DDG1.D.4 **Status:** Closed

Alert summary Alert Problem details **Final report details** Contributions Involved CA's History

Outcomes The issue is solved. Product discarded and not in use.

Print Back

NOTIFICATIONS/REMINDERS

- The notification will be done via email and will contain only a link to redirect the user to the alert detail/personal data
- When the user will be notified by email?
 - When the alert is submitted to the CA and other stakeholders
 - Each time a comment is added to the alert (by notified / affected CA)
 - Each time the alert is forwarded to another CA (by notified / affected CA)
 - Each time the alert is updated by the CA initiator
 - When a notified CA confirm or not he is affected by the alert
 - When a CA is assigned to write the final report
 - When the final report is submitted for comments (only to affected CA)
 - When the alert or the final report is closed (all notified CA and other stakeholders)
- When the user will receive a reminder?
 - **5 days** after submission for confirmation to be affected, to remind the **CA to confirm or not** (4 times 5 days – after is per default not affected)
 - **10 days** after the submission for comments of the final report, to remind the **CA** to provide comments
 - **Once per month** to remind a Competent Authority to check RATC for news.

RAB DATA PROTECTION

1. Data Protection Notification (linked to RATC)
2. Privacy Statements for Users

RAB SUPPORT

1. Functional mailbox SANCO-RAB@ec.europa.ec
2. Help/Frontdesk dedicated to RAB – technical and operational questions.
3. Quick User Manual by January 2014
4. SoHO team to provide support on business questions.

RAB STANDARD OPERATING PROCEDURES (1)

1. RAB SOP as reference document
2. Available to all RAB users
3. In line with the RAB Workflow and User Manual

RAB STANDARD OPERATING PROCEDURES (1)

- ◆ **Type of Alerts:** The alerts can be related to:
 - outbreaks of communicable diseases;
 - defects of Medical devices, tests;
 - defects on products used for processing blood or blood products;
 - import and export issues of blood products;
 - Other types.

- ◆ **Criteria to report an alert using the RASB are:**
 - Quality/Safety perspective for blood of a serious or potentially serious nature;
 - A known risk to patients, or potential patients, in Member States;
 - With wider public health implications.

RAB CASE STUDIES (HANDS-ON)

1. Scenarios (alerts already submitted)
2. One country each user
3. Play as in a real alert

RAB: NEXT STEPS

1. RAB launched on the first week of February 2014
2. First training course 15th January 2014 in Brussels; 15 Member States
3. Second Training course April 2014.
4. CIRCABC as back-up system
5. Alive project – the platform hosts Blood and T&C

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And to the Experts of the RAB WG

Thank you



Avertissement

- Lien d'intérêt : personnel salarié de l'ANSM (opérateur de l'Etat).
- La présente intervention s'inscrit dans un strict respect d'indépendance et d'impartialité de l'ANSM vis-à-vis des autres intervenants.
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