# REGISTRATION REPORT

## Part A

## Risk Management

**Product code: FH-045**

**Product name: NAUTIUS**

**Active Substance(s):**

**Thifensulfuron-methyl, 400 g/kg**

**Tribenuron-methyl, 150 g/kg**

**COUNTRY: FRANCE**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(marketing authorisation)**

**Applicant: Rotam Agrochemical Europe Ltd**

**Date: 01/03/2016**

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**PART A – Risk Management**

The company Rotam Agrochemical Europe Ltd has requested marketing authorisation in France for the product NAUTIUS (formulation code: FH-045), containing 400 g/kg thifensulfuron-methyl and 150 g/kg tribenuron-methyl for use as an herbicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to NAUTIUS where that data have not been considered in the EU review process. Otherwise assessments for the safe use of NAUTIUS have been made using endpoints agreed in the EU review of both thifensulfuron-methyl and tribenuron-methyl.

This document describes the specific conditions of use and labelling required for France for the registration of NAUTIUS.

Appendix 1 of this document provides a copy of the French decision.

Appendix 2 of this document is a copy of the draft product label as proposed by the applicant.

Appendix 3 of this document is a copy of the letter(s) of access.

## 1 DETAILS OF THE APPLICATION

### 1.1 Application background

The present registration report concerns the evaluation of Rotam Agrochemical Europe Ltd's application to market NAUTIUS in France as an herbicide (product uses described under point 2.3). France acted as a Zonal rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

### 1.2 Active substance approval

***Thifensulfuron-methyl***

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| Commission Directive 2001/99/EC of 20 November 2001 amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include glyphosate and thifensulfuron-methyl as active substances.<br><br>Commission Directive 2010/77/EU of 10 November 2010 amending Council Directive 91/414/EEC as regards the expiry dates for inclusion in Annex I of certain active substances.<br><br>Regulations Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. |
| Specific provisions of regulation were as follows :<br><br>PART A<br><br>Only uses as herbicide may be authorised<br><br>PART B<br><br>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on thifensulfuron-methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 29 June 2001 shall be taken into account. In this overall assessment Member States:<br><br>—must pay particular attention to the protection of groundwater; |

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| —must pay particular attention to the impact on aquatic plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures. |
| There is no definitive EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance.<br><br>A Review Report is available (SANCO/7577/VI/97-final, 12 December 2001). |

***Please note that new conclusions (EFSA Journal 2015;13(7):4201) have been published last 23rd July 2015 and therefore was not considered in the assessment.***

***Tribenuron (variant tribenuron-methyl)***

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| Commission Directive 2005/54/EC of 19 September 2005 amending Council Directive 91/414/EEC to include tribenuron as active substance<br><br>Regulations Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.<br><br>Commission Implementing Regulation (EU) No 533/2013 of 10 June 2013 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-methyl-cyclopropene, chlorothalonil, chlorotoluron, cypermethrin, daminozide, forchlorfenuron, indoxacarb, thiophanate-methyl and tribenuron. |
| Specific provisions of regulation were as follows :<br><br>PART A<br><br>Only uses as herbicide may be authorised<br>PART B<br><br>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tribenuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 February 2005 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of non-target terrestrial plants, higher aquatic plants and groundwater in vulnerable situations. Conditions of authorisation should include risk mitigation measures, where appropriate. |
| An EFSA conclusion is available (EFSA Scientific Report (2004) 15, 1-5).<br>A Review Report is available (SANCO/10671/04 final, 15 February 2005). |

### 1.3 Regulatory Approach

The present application (2012-1169) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

According to the French law and procedures, specific conditions of use are set in the decision letter.
The French Order of 12 September 2006[3] provides that:

- unless formaly stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formaly stated in the product authorisation, the minimum buffer zone alongside a water body is 5 m;
- unless formally stated in the product authorisation, the minimum reentry delay is 6 hours for field uses and 8 hours

[1] French Food Safety Agency, Afssa, before 1 July 2010
[2] SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5
[3] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000425570

for indoor uses.
Drift reduction measures such as low-drift nozzles are not considered within the decision making process in France. However, drift buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French order.

The current document (RR) based on Anses' assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[4], implementing regulations and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Last, the French Order of 26 March 2014[6] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the decision.
- the "reference" and "linked" crops are defined in Appendix 1 of that French order.

Then, at FR level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to linked" ones are assessed even if not clearly intended by applicant in the dRR, and a conclusion is reached on acceptability of intended uses on those linked crops. The aim of this order, mainly based on the EU document on residue data extrapolation[7] is to supply minor crops with registered PPP.

Then, the GAPs table (Section 2.3.) and decision may include uses on crops not clearly intended by applicant.

The decision, as duplicated in Appendix 1, takes also into account national provisions, including national mitigation measures.

### 1.4 Data Protection Claims

Where protection for data is being claimed for information supporting registration of NAUTIUS, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

### 1.5 Letter(s) of Access

Thifensulfuron-methyl: Not necessary: the applicant has provided sufficient data to show that access is not required.

Tribenuron-methyl:

The applicant has provided equivalent studies to the notifier's Annex II dossier.

For section 5, Environmental fate and behaviour, the applicant has provided the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Section 5. A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

[4] REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
[5] COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products
[6] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo
[7] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

# 2 DETAILS OF THE AUTHORISATION

## 2.1 Product Identity

| | |
|---|---|
| **Product name (code)** | NAUTIUS (FH-045) |
| **Authorisation number** | N/A : no acceptable use at FR level |
| **Function** | Herbicide |
| **Applicant** | Rotam Agrochemical Europe Ltd |
| **Composition** | 400 g/kg thifensulfuron-methyl<br>150 g/kg tribenuron-methyl |
| **Formulation type (code)** | Water dispersible granules (WG) |
| **Packaging** | HDPE (100 g, 200 g, 240 g, 400 g, 500 g, 800 g) |

## 2.2 Classification and Labelling

### 2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

For information:

| | | |
|---|---|---|
| **Physical hazards** | - | |
| **Health hazards** | - | - |
| **Environmental hazards** | N | Dangerous for the environment |

| | | |
|---|---|---|
| **Risk phrases** | R50/53 | Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. |
| **Safety phrases** | S60 | This material and its container must be disposed of as hazardous waste. |
| | S61 | Avoid release to the environment. Refer to special instructions/safety data sheets. |

### 2.2.2 Classification and labelling in accordance with Regulation (EC) No1272/2008

| | |
|---|---|
| **Physical hazards** | - |
| **Health hazards** | - |
| **Environmental hazards** | Aquatic Acute 1<br>Aquatic Chronic 1 |
| **Hazard pictograms** |  |

| | | |
|---|---|---|
| **Signal word** | Warning | |
| **Hazard statements** | H400 | Very toxic to aquatic life. |
| | H410 | Very toxic to aquatic life with long lasting effects. |
| **Precautionary statements –** | ***For the P phrases, refer to the extant legislation*** | |
| **Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)** | EUH208 | Contains tribenuron-methyl. May produce an allergic reaction. |

***See Part C for justifications of the classification and labelling proposals.***

### 2.2.3 Other phrases in compliance with Regulation (EU) No 547/2011

### 2.2.4 N/A: no acceptable useOther phrases linked to the preparation

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N/A: no acceptable use

## 2.3 Product uses

**Please note:**
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
Use should be crossed out when the applicant no longer supports this use.

**GAP rev. 1, date: 2016-03-01**

| | | | |
|---|---|---|---|
| **PPP (product name/code)** | **NAUTIUS (FH-045)** | **Formulation type:** | **WG** |
| **active substance 1** | **thifensulfuron-methyl** | **Conc. of as 1:** | **400 g/kg** |
| **active substance 2** | **tribenuron-methyl** | **Conc. of as 2:** | **150 g/kg** |
| **Applicant:** | **Rotam Agrochemical Europe Ltd** | **professional use** | ☒ |
| **Zone(s):** | **Southern** | **non professional use** | ☐ |

**Verified by MS: Yes**

| **Crop and/ or situation** (a) | **Zone** | **Product code** | **F G or I** (b) | **Pests or Group of pests controlled** (c) | **Formulation** | | **Application** | | | | **Application rate per treatment** | | | **PHI (days)** (l) | **Remarks:** (m) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | **Type** (d-f) | **Conc. of as** (i) | **method kind** (f-h) | **growth stage & season** (j) | **number min max** (k) | **interval between applications (min)** | **kg as/hL min max** | **water L/ha min max** | **kg as/ha min max** | | |
| Winter and spring cereals (wheat, barley, durum wheat, triticale, oats and rye) | Southern zone | FH-045 | F | Dicotyledonous weeds | WG | 400 g/kg TSM<br>150 g/kg TBM | Foliar spray | BBCH 13-39 (spring) | Max 1 | - | TSM: 0.01-0.02<br>TBM: 0.003-0.0075 | 200-400 | TSM: 0.032-0.040<br>TBM: 0.012-0.015 | N/A | Not acceptable (no interest compared to the French standard)<br>Risk to groundwaters (data gap to assess the toxicological relevance of two metabolites) |

**Remarks:**

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

# 3 RISK MANAGEMENT

## 3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

### 3.1.1 Physical and chemical properties

The formulation NAUTIUS (FH-45) is water dispersible granules (WG). All studies have been performed in accordance with the current requirements. The appearance of the formulation is an off white with mild characteristic odour granules. It is not explosive and has no oxidizing properties. It has no self ignition temperature below 400°C. In aqueous solution (1%), its pH is 5.0 at 25°C. Stability data indicate a shelf life of at least 2 years at ambient temperature (HDPE). Its technical characteristics are acceptable for a water dispersible granules (WG) formulation. The formulation must be stored at ambient temperature.

### 3.1.2 Methods of analysis

Analytical methods for the determination of active substances in the formulation are available and validated.

Analytical methods are available in the monographs and in this dossier and validated for the determination of residues of thifensulfuron methyl and tribenuron methyl in plants (dry commodities), soil, water (surface and drinking) and air. Analytical methods for the determination of residues of thifensulfuron methyl and tribenuron methyl in foodstuff of animal origin are not necessary as no MRL has been set.

To update the dossier and to be in accordance with SANCO 825/00/rev8.1, an analytical method for the determination of thifensulfuron-methyl in soil should be provided at re-approbation of the active substance.

The active substances are neither toxic, nor very toxic, hence no analytical method is required for the determination of resides in biological fluids and tissues.

### 3.1.3 Mammalian Toxicology

#### 3.1.3.1 Acute Toxicity

NAUTIUS containing 400 g/kg thifensulfuron-methyl and 150 g/kg tribenuron-methyl has a low toxicity in respect to acute oral (LD50 > 2000 mg/kg bw), inhalation (LC50 > 3.46 mg/L/4 h) and dermal toxicity (LD50 > 2000 mg/kg bw) and is not irritating to the rabbit skin or eye and is not a skin sensitiser.

#### 3.1.3.2 Operator Exposure

Operator exposure was assessed against the AOEL agreed in the EU review of thifensulfuron-methyl and tribenuron-methyl. Data on dermal absorption of NAUTIUS was provided and considered acceptable.

| **Endpoint used in assessment for NAUTIUS** | |
|---|---|
| Thifensulfuron methyl | |
| Systemic AOEL : | 0.07 mg/kg bw/d |
| Dermal absorption of undiluted product: | 100 % |
| Dermal absorption of diluted product: | 100 % |
| Tribenuron methyl | |
| Systemic AOEL : | 0.07 mg/kg bw/d |
| Dermal absorption of undiluted product: | 3.1 % |
| Dermal absorption of diluted product: | 100 % |

Operator exposure was modelled using the German BBA model:

| Parameters used in operator exposure assessment | | | | | |
|---|---|---|---|---|---|
| Crop | Equipment | Application rate kg product/ha (g a.s./ha) | | Spray dilution (L/ha) | Model used |
| **Open field** | | | | | |
| Cereals | Tractor-mounted/trailed boom sprayer, hydraulic nozzles | Thifensulfuron methyl 0.1 kg/ha (40 g/ha) | Tribenuron methyl 0.1 kg/ha (15 g/ha) | 200-400 | BBA |

According to the model calculations, it can be concluded that the risk for the operator using NAUTIUS on field crops is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.

The following personal protective equipment is recommended by applicant:

- For mixing/loading
  - Nitrile gloves certified EN 374-3;
  - Working coverall 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment;
  - Long-sleeved apron, Category III Type PB3 worn over the coverall proposed above;
- For application _ Downward spraying
  *If application with tractor with cab*
  - Working coveralls 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment;
  - Disposable nitrile gloves certified EN 374-2 in the case of an intervention on application equipment, but not inside the cab. In the case of an intervention on application equipment, it should be noted that gloves should be worn only outside the tractor cab and stored after use outside the cab

  *If application with tractor without cab*
  - Working coveralls 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment;
  - Disposable nitrile gloves certified EN 374-2 in the case of an intervention on application equipment;
- For equipment cleaning
  - Nitrile gloves certified EN 374-3;
  - Working coverall 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment;
  - Long-sleeved apron, Category III Type PB3 worn over the coverall proposed above.

#### 3.1.3.3 Bystander Exposure

Bystander exposure has been assessed according to the EUROPOEM II for the use of NAUTIUS. It is concluded that there is no undue risk to the bystander after incidental short-term exposure to NAUTIUS.

#### 3.1.3.4 Worker Exposure

NAUTIUS is used as herbicidal treatment on cereals at a very early growth stage (BBCH 13-39) where there is no need to re-enter the treated area after application. Worker exposure is considered not relevant.

**Toxicological relevance of the metabolites according to SANCO/221/2000**[8]

Metabolites of thifensulfuron-methyl:

- Metabolites IN-L9225 and IN-L9223 are not relevant based on toxicological data.
- It is not possible to conclude for metabolites IN-V7160, IN-A5546 and IN-W8268 (data gap).

Metabolite of tribenuron-methyl:

- IN-00581 is not relevant based on toxicological data.
- It is not possible to conclude for metabolites IN-A4098 and IN-R9805 (data gap).

**Metabolite Exposure assessment**

For NAUTIUS plant protection product, maximum groundwater concentrations of 1 metabolite of thifensulfuron-methyl (IN-L9225: thifensulfuron acid) and 1 metabolite of tribenuron-methyl (IN-00581: saccharine) were shown to exceed the threshold of 0.75 µg/L. A refined risk assessment is thus needed for IN-L9225 and IN-00581.

[8] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. SANCO/221/2000-rev10-final, 25 February 2003.

| | Metabolites | Maximum level in groundwater (µg/L) | Theoretical ingestion | |
|---|---|---|---|---|
| | | | µg/day | µg/kg bw/day |
| | **Adult, 60 kg bw, 2L/day water consumption:** | | | |
| NAUTIUS | IN-L9225 | 1.138 | 2.276 | 0.0379 |
| | IN-00581 | 0.998 | 1.996 | 0.0333 |

The maximum theoretical ingestion of IN-L9225 metabolite (0.0379 µg/kg bw/d for IN-L9225) is widely lower than its ADI (0.01 mg/kg bw/d). Therefore the metabolite is not expected to be a safety concern.
The maximum theoretical ingestion of IN-00581 metabolite (0.0333 µg/kg bw/d for IN-L9225) is widely lower than its ADI (3.8 mg/kg bw/d). Therefore the metabolite is not expected to be a safety concern.

### 3.1.4 Residues and Consumer Exposure

#### 3.1.4.1 Residues

Primary crop metabolisms were sufficiently investigated to define residue of both active substances for enforcement and risk assessment in crops under consideration.

Regarding the magnitude of residues in cereals (wheat, barley, rye, oat, triticale), a sufficient number of residue trials are available to support the intended GAPs in France. These data allowed to consider that no quantifiable residues of thifensulfuron-methyl or tribenuron-methyl will be present in cereal grains, and to confirm that no MRL exceedance will result from intended uses.

As residues of both active substances do not exceed the trigger value of 0.1 mg/kg in cereal grains, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated; it is very unlikely that residues of thifensulfuron-methyl or tribenuron-methyl will be present in succeeding crops.

For thifensulfuron-methyl, the residue data on cereals do not modify the dietary burden for beef, dairy cattle and pig. The trigger value is still not reached for poultry. According to animal metabolism study, no significant residue levels of thifensulfuron-methyl are expected in ruminants or pig commodities when crops are treated according to the intended GAPs. Therefore, it can be concluded that there is still no need to propose MRL for foods of animal origin.
For tribenuron-methyl, considering dietary burden and based on the intended uses, no significant intake above the trigger value of 0.1 mg kg/dm was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

#### 3.1.4.2 Consumer exposure

The toxicological profile of thifensulfuron-methyl and tribenuron-methyl were evaluated at EU level, which resulted in the proposal of ADIs (0.01 mg/kg for both thifensulfuron-methyl and tribenuron-methyl) and ARfD (0.2 mg/kg for tribenuron-methyl, not necessary for thifensulfuron-methyl) that were considered in the frame of this evaluation.
Chronic consumer exposure resulting from the uses proposed in the framework of this application was calculated for both active substances, whereas acute consumer exposure was calculated for tribenuron-methyl only. Based on EFSA PRIMo (rev2), chronic and acute exposures were considered as acceptable for all groups of consumers.

### 3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation has been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs for the active substances tribenuron-methyl, thifensulfuron-methyl and their metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC of tribenuron-methyl, thifensulfuron-methyl and their metabolites in soil, surface water and groundwater has been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU review or agreed in the assessment based on new data provided.

PECsoil and PECsw derived for the active substances and their metabolites are used for the eco-toxicological risk assessment, and mitigation measures are proposed.

**Under acidic conditions**, for all the intended uses, PECgw for tribenuron-methyl and its metabolites IN-L5296 do not exceed the trigger of 0.1 µg/L for all the European scenarios. The PECgw for the metabolites IN-A4098, IN-00581 and IN-R8905 do not exceed the trigger of 10 µg/L for all scenarios. According to guidance document SANCO/221/2000, metabolites IN-A4098, IN-00581 and IN-R8905 are not considered as relevant. Therefore, no unacceptable risk of groundwater contamination is expected under acidic conditions for all the intended uses.

**Under alkaline conditions**, for a single application every year on winter cereals in spring, PECgw for tribenuron-methyl exceed the trigger of 0.1 µg/L for at least 6 scenarios.
For a single application every third year in spring, PECgw for tribenuron-methyl and its metabolite IN-L5296 do not exceed the trigger of 0.1 µg/L for all scenarios.
Therefore, no unacceptable risk of groundwater contamination is expected under alkaline conditions only when applied every third year in spring.

For a single application every year on spring cereals, PECgw for tribenuron-methyl exceed the trigger of 0.1 µg/L for at least 5 out of 6 scenarios. For a single application every third year, PECgw for tribenuron-methyl exceed the trigger of 0.1 µg/L for 5 out of 6 scenarios. Therefore, no acceptable risk of groundwater contamination is expected under alkaline conditions.

Based on the simulations proposed by the notifier and additional simulations performed by zRMS, the PECgw calculated for thifensulfuron-methyl, IN-A4098, IN-L9226 and IN-A5546 are below the regulatory threshold of 0.1 µg/L for all the European scenarios (maximal respective values of < 0.001 µg/L; 0.003 µg/L; < 0.001 µg/L and 0.059 µg/L) for all intended uses.

The PECgw calculated for the metabolites IN-L9225, and IN-L9223 exceed 0.1 µg/L for at least one representative European scenario (maximal respective values of 1.138 µg/L; and 0.741 µg/L). As these metabolites are not relevant according to the guidance document SANCO/221/2000, no unacceptable risk of groundwater contamination is identified for the metabolites IN-L9225, and IN-L9223.

The PECgw calculated for the metabolites IN-V7160 and IN-W8268 exceed 0.1 µg/L for at least one representative European scenario (maximal respective values of 1.193 µg/L; and 4.937 µg/L). As no information on their relevance is available according to the guidance document SANCO/221/2000, no acceptable risk of groundwater contamination is identified for the metabolites IN-V7160 and IN-W8268.

Based on vapour pressures, information on volatilisation from plants and soil, and DT50 calculations, no significant contamination of the air compartment is expected for the intended uses for both active substances.

### 3.1.6 Ecotoxicology

**Birds**
The acute and reproductive TER values for birds are higher than the triggers of 10 and 5, respectively. It can therefore be concluded to an acceptable risk to birds for the proposed use of FH-045.

**Mammals**
The acute and reproductive TER values for mammals are higher than the triggers of 10 and 5, respectively and therefore an acceptable risk to mammals is expected from the proposed use of FH-045.

**Aquatic organisms**
TER values for fish, aquatic invertebrates, algae and aquatic macrophytes are above the relevant triggers indicating that application of the formulation FH-045 according the GAP should pose acceptable risks to aquatic organisms when :

- a 5 m vegetated buffer zone is used for spring cereals,
- a 20 m vegetated buffer zone is used for winter cereals,
- the product is not applied on drained soil for spring and winter cereals.

**Bees**
The oral and contact hazard quotients for both active substances and the preparation are below the trigger of 50 and thus an acceptable risk to bees is expected from the proposed use of FH-045.

**Non-target arthropods other than bees**
The hazard quotients for in-field and off-field exposure for are below the trigger of 2. This indicates an acceptable risk to non-target arthropods.

**Earthworms and other soil non-target macro-organisms**
All the acute and long-term TER values exceed the triggers value, indicating that FH-045 pose an acceptable risk to earthworms and non-target macro-organisms other than earthworms.

**Non-target soil micro-organisms**
No effects of the active substances and the metabolites IN-L5296 and IN-00581 on soil non-target micro-organisms are expected for exposure higher than the PEC soil. This indicates that FH-045 pose an acceptable risk to earthworms and non-target macro-organisms other than earthworms.

**Non-target plants**
Based on a refined risk assessment, the use of FH-045 is considered to pose an acceptable risk to non-target plants in off-crop areas, provided that a protective buffer strip of 50 m is considered.

### 3.1.7 Efficacy

From the different trials, the product FH-045 applied at 0.1 or 0.08 kg/ha offered the same control of weeds as the different reference products. Even at the lower dose of 0.08 kg/ha, the product FH045 supplies more TSM (7-to 15 g/ha) than the national tested reference product containing TSM and TBM.
So the use of this product for the control of weeds in cereals doesn't present any interest regarding the each national standard.

The selectivity of FH-045 on the intended winter and spring cereals when applied at BBCH 20-32 is considered as satisfactory.
The selectivity of FH-045 on the intended winter and spring cereals when applied at BBCH 13-20 is considered as partially demonstrated. Additional data are necessary to confirm the good selectivity of the product on young stage of development of spring cereals.

The risk of negative impact (yield, quality, transformation processes) is considered as negligible.

Recommendations of use were established for following crops and adjacent crops.

The risk of resistance development or appearance is considered as medium on dicots. So, only one application per season and per year is recommended.

## 3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation cannot be granted because:

- the use of this product for the control of weeds in cereals doesn't present any interest regarding the each national standard;
- and no acceptable risk of groundwater contamination is identified for the metabolites IN-V7160 and IN-W8268 of thifensulfuron-methyl since there is a data gap to assess their toxicological relevance according to the guidance document SANCO/221/2000.

A copy of the decision issued can be found in Appendix 1 – Copy of the product decision.

## 3.3 Substances of concern for national monitoring

No information stated.

## 3.4 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

### 3.4.1 Post-authorisation monitoring

N/A

### 3.4.2 Post-authorisation data requirements

N/A

### 3.4.3 Data gaps

### 3.4.4 Label amendments (see label in Appendix 2):

N/A

**Appendix 1 – Copy of the French decision**

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anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

## Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

*Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,*

*Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,*

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique* ***NAUTIUS***

*de la société* *ROTAM AGROCHEMICAL EUROPE LIMITED*

*enregistrée sous le* *n°2012-1169*

*Vu les conclusions de l'évaluation du 08 décembre 2015,*

*Considérant que les doses d'emploi du produit n'ont pas été justifiées,*
*Considérant qu'en l'absence de données suffisantes, le risque de contamination des eaux souterraines n'a pu être finalisé,*

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

*NAUTIUS*

*Page 1 sur 2*

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| **Informations générales sur le produit** | |
|---|---|
| **Nom du produit** | NAUTIUS |
| **Type de produit** | Produit de référence |
| **Titulaire** | ROTAM AGROCHEMICAL EUROPE LIMITED<br>Hamilton House, Mabledon Place<br>London, WC1H 9BB<br>ROYAUME-UNI |
| **Formulation** | Granulés dispersables dans l'eau (WG) |
| Contenant | 400 g/kg - thifensulfuron-méthyle<br>150 g/kg - tribénuron-méthyle |
| **Numéro d'intrant** | 966-2012.01 |
| **Fonction** | Herbicide |
| **Gamme d'usages** | Professionnel |

A Maisons-Alfort, le 01 MARS 2016

**Françoise WEBER**
Directrice générale adjointe des produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

*NAUTIUS*

*Page 2 sur 2*

**Appendix 2 – Copy of the draft product label as proposed by the applicant**

# NAUTIUS®

**HERBICIDE ANTIDICOTYLEDONES ANNUELLES ET VIVACES DES CEREALES**

**Granulés à disperser dans l'eau (WG)**
400 g/kg thifensulfuron-méthyle + 150 g/kg tribénuron-méthyle

**Homologation n° XXXXXX**
**ROTAM AGROCHEMICAL EUROPE LIMITED**

**N: Dangereux pour l'environnement**

| | |
|---|---|
| R50/53 | Très toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique |
| | Respectez les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement. |
| S35 | Ne se débarrasser de ce produit et de son récipient qu'en prenant toutes précautions d'usage |
| S57 | Utiliser un récipient approprié pour éviter toute contamination du milieu ambiant |
| S61 | Eviter le rejet dans l'environnement. Consulter les instructions spéciales / la fiche de données de sécurité |
| SP1 | Ne pas polluer l'eau avec le produit ou son emballage. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes. |

Homologation n°: XXXXX
Rotam Agrochemical Europe Ltd
Camrascan House, Minerva Business Park,
Peterborough, PE2 6QR - UK

Distribué par : xxxxxxx

Conditionnement: XXXX
Lot n°: XXXX

**Fiche de données de sécurité disponible sur http://www.quickfds.com**

Réemploi de l'emballage interdit ; rincer soigneusement le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur, ou dans la cuve de rinçage pour l'injection directe.

Éliminer les emballages vides via une collecte organisée par un service de collecte spécifique. Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

**MODE D'ACTION**

NAUTIUS est absorbé par les feuilles puis est véhiculé par systémie ascendante et descendante vers les méristèmes au niveau desquels il bloque la division cellulaire. Il agit par inhibition de l'enzyme acétolactate synthase (ALS), indispensable à la synthèse de plusieurs acides aminés : leucine, isoleucine et valine. NAUTIUS induit rapidement un arrêt de la croissance des adventices sensibles (principalement des dicotylédones), qui disparaissent 3 à 6 semaines après le traitement.
NAUTIUS appartient à la famille des sulfonylurées et est classé dans le groupe B de l'HRAC.

**EFFICACITE**

NAUTIUS s'utilise au printemps en désherbage précoce, après la levée des adventices du stade 3 feuilles étalées (BBCH 13) au stade dernière feuille développée (BBCH 39) de la culture.
Il s'applique avec des volumes d'eau compris entre 200 et 400 litres/ha.

| Culture | Dose (g/ha) | Nombre de traitements/ha/an | Zone non traitée (ZNT) |
|---|---|---|---|
| Avoine d'hiver | 80-100 | 1 | 10 mètres |
| Avoine de printemps | 80-100 | 1 | 10 mètres |
| Blé dur d'hiver | 80-100 | 1 | 10 mètres |
| Blé dur de printemps | 80-100 | 1 | 10 mètres |
| Blé tendre d'hiver | 80-100 | 1 | 10 mètres |
| Blé tendre de printemps | 80-100 | 1 | 10 mètres |
| Seigle d'hiver | 80-100 | 1 | 10 mètres |
| Triticale | 80-100 | 1 | 10 mètres |
| Orge d'hiver | 80-100 | 1 | 10 mètres |
| Orge de printemps | 80-100 | 1 | 10 mètres |

NAUTIUS est sélectif de toutes les variétés actuelles de blé dur d'hiver et de printemps, blé tendre d'hiver et de printemps, avoine d'hiver et de printemps, orge d'hiver et de printemps, seigle d'hiver et triticale. Il est efficace sur un grand nombre d'adventices dicotylédones. Son efficacité est optimale sur mauvaise herbes jeunes lorsque la végétation est poussante.
NAUTIUS est efficace sur de nombreuses adventices dicotylédones : Anthémis, Chou noir, Calepine, Capselle, Coquelicot, Chénopode, Géranium, Gaillet, Lamiers, Matricaires, Myosotis, Mouron des oiseaux, Mouron rouge, Moutarde, Ortie brûlante, Pensée sauvage, Sisymbres, Renouées, Trèfle blanc, Véronique de Perse.

Les adventices sensibles changent de couleur puis se dessèchent progressivement, généralement entre 2 et 4 semaines après l'application.

Doses
Les doses de NAUTIUS s'élèvent à 80-100 g/ha.

**CONDITIONS D'EMPLOI**

Avertissement
« L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation.»

- Ne pas utiliser NAUTIUS à une dose supérieure à sa dose maximale homologuée : 100 g/ha au printemps;
- Pour protéger les eaux souterraines, ne pas appliquer la préparation NAUTIUS, ou tout autre préparation contenant du tifensulfuron-méthyle et/ou du tribénuron-méthyl, plus d'une fois dans la même parcelle ;
- Appliquer NAUTIUS sur des mauvaises herbes jeunes et en croissance active ;
- Compte tenu de la phytotoxicité de la préparation sur les plantes dicotylédones, il conviendra de limiter la dérive de la pulvérisation vers les cultures adjacentes, et respecter une zone non traité de 5 mètres.

Les limites maximales de résidus applicables dans les pays de l'Espace Economique Européen sont consultables à l'adresse suivante : http://ec.europa.eu/sanco_pesticides/public/index.cfm. Pour les autres pays susceptibles d'importer les denrées traitées, il est de la responsabilité de l'utilisateur et de l'exportateur d'assurer la conformité en matière de quantité de résidus.

Préparation de la bouillie
- Vérifier le bon état du matériel de pulvérisation. Utiliser de préférence des buses à jet pinceau et à basse pression.
- S'assurer que la cuve ne contient aucun résidu de traitement précédent.
- Remplir la cuve à moitié d'eau et verser NAUTIUS directement dans la cuve.
- Mettre l'agitation en marche et finir le remplissage.
- En cas de mélange :
    - Avec un produit formulé sous forme de concentré émulsionnable (EC), introduire NAUTIUS en premier, attendre sa mise en solution puis ajouter le produit partenaire ;
    - Avec un produit formulé sous forme de suspension concentrée (SC), introduire le produit partenaire en premier, attendre sa mise en solution puis ajouter NAUTIUS.
- Ne préparer que la quantité de bouillie nécessaire à la superficie à traiter.
- Surveiller le remplissage afin d'éviter tout débordement.
- Eviter toute contamination des eaux lors de la préparation du traitement et du rinçage des emballages.

**COMPATIBILITE**

Seuls les mélanges autorisés peuvent être utilisés. Tout mélange doit être préalablement testé. Nos recommandations tiennent compte des informations disponibles à la date de fabrication du produit.

**PRECAUTIONS D'EMPLOI**

- Traiter une culture en bon état végétatif. Ne pas appliquer NAUTIUS sur une céréale souffrant d'un stress consécutif à la sècheresse, à l'excès d'eau, à des températures trop basses, à une attaque parasitaire, à une carence minérale ou à tout autre facteur ayant réduit sa croissance.
- Ne pas traiter une céréale sous ensemencée avec une culture dicotylédone.
- L'application de NAUTIUS convient à tout type de sol.
- Ne pas appliquer NAUTIUS sur une céréale en séquence ou en mélange avec une autre spécialité herbicide à base de sulfonylurée.
- Appliquer sur une végétation sèche.
- Traiter par temps calme et sans vent afin d'éviter l'entraînement de l'herbicide sur des cultures sensibles.
- S'assurer que la bouillie herbicide ne débordera pas la surface à désherber.
- Si des risques de ruissellement existent il faut laisser une bande enherbée pour éviter l'entraînement de l'herbicide vers des points d'eau.
- Ne pas respirer les brouillards de pulvérisation. Ne pas appliquer en cas de vent ou de pluie.
- Se laver les mains et le visage dès la fin du traitement, et avant toute prise de nourriture. Stocker hors de portée des enfants et dans l'emballage d'origine.

**Après l'application**

Rinçage du pulvérisateur
Immédiatement après utilisation de NAUTIUS, le nettoyage du pulvérisateur selon la procédure est obligatoire.

## Nettoyage du matériel de pulvérisation

**1 VIDER**

Vider complètement le pulvérisateur (en appliquant sur la parcelle).

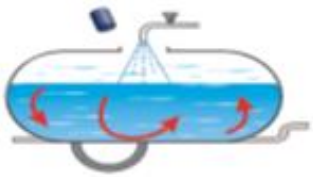
**2 DILUER**

Diluer 5 fois minimum le volume de bouillie restant dans la cuve et l'épandre sur la parcelle traitée.

**3 RINCER**

Rincer **IMMEDIATEMENT** soigneusement l'intérieur de la cuve (sans oublier la paroi du haut de la cuve) à l'eau claire et faire passer à travers les tuyaux et les rampes une quantité d'eau au moins égale à 10 % de la capacité de la cuve (ex. 60 litres si cuve de 600 litres). Ensuite vider complètement le pulvérisateur.

## Nettoyage du matériel de pulvérisation



**4 PRODUIT NETTOYANT RECOMMANDÉ**

Utiliser uniquement des produits recommandés pour le nettoyage des sulfonylurées dans les pulvérisateurs.
**1.** Remplir la cuve à moitié d'eau. Ajouter le produit nettoyant à la dose préconisée par le fabricant.
**2.** Mettre l'agitateur en marche et faire circuler un peu de cette solution concentrée dans les tuyaux et les rampes.
**3.** Terminer le remplissage complet de la cuve et laisser agir 2 heures.
Vider ensuite complètement le pulvérisateur.

**5 NETTOYER**

Les jets et filtres doivent être démontés et nettoyés séparément avec une solution à base du même produit nettoyant.

**6 RINCER**

Rincer la cuve à l'eau claire et faire passer à travers les tuyaux et rampes une quantité d'eau au moins égale à 10 % de la capacité de la cuve (ex. : 60 litres si cuve de 600 litres).
Vider complètement.
Répéter le rinçage si nécessaire jusqu'à la disparition complète du traceur.

L'élimination des eaux de vidange ou de rinçage (effluents) doit se faire en respectant la législation en vigueur.

**CULTURES SUIVANTES DANS LA ROTATION**

A la suite d'une application de NAUTIUS à sa dose recommandée il est possible de semer l'une des cultures ci-après dans le cadre normal de la rotation:

| Automne suivant la récolte de la céréale | Printemps suivant la récolte de la céréale |
|---|---|
| Pas de restriction | Pas de restriction |

**CULTURES DE REMPLACEMENT**

En cas de destruction accidentelle de la céréale traitée avec NAUTIUS il n'est possible de semer, après labour que des céréales de printemps à petits grains.

**IMPORTANT**

Respecter les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage. Elles ont été déterminées en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé.

Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces…

Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture.

® Marque déposée du groupe ROTAM

**Appendix 3 – Letter(s) of Access**

HELM

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HAMBURG, 04.02.2014

DEPARTMENT Regulatory Affairs Europe
CB/CB

YOUR REFERENCE: DATED:

TELEPHONE-DIRECT-NO.: +49-40/2375-
E-MAIL: C.Blaschke@helmag.com

**Lettre d'accès pour NAUTIUS, n° réf. 2012-1169**
**Date de la demande de compléments : 06/11/2013**
**Substance active : Tribenuron-methyl**

Madame, Monsieur,

Par la présente nous, Helm AG, Nordkanalstraße 28, 20097 Hamburg, Germany, vous envoyons la lettre d'accès à notre dossier de TRIMEO (n° réf : 2012-0803) pour supporter la demande d'homologation de ROTAM pour Nautius (N° réf : 2012-1169).

La section 5 du dossier de TRIMEO était mise à jour suite à la réception de votre courrier daté le 12/02/2013. Les pièces complémentaires étaient soumis à Anses en mai 2013, l'accusé réception d'Anses est daté le 23/05/2013.

Ce présent lettre d'accès est limité **exclusivement** à la section dRR Part B, Section 5, IIIA1 9.6 (**$PEC_{gw}$**), y inclus Appendix 3 and Appendix 4.

Comme décrit dans la lettre d'accès ni Rotam, ni ses employés sont autorisés de recevoir des copies des informations du dossier (proprietary data) de Helm, de les lire ou de les réviser.

Les informations complémentaires demandés au-delà de la $PEC_{gw}$ seront fournies directement de Rotam.

Veuillez agréer, Madame, Monsieur, l'assurance de nos salutations distinguées.

HELM AG, Nordkanalstraße 28, 20097 Hamburg, Germany

HELM HELM AG
Nordkanalstr. 28, 20097 Hamburg
Telefon: 040 / 23 75 - 0

Dr. Diana Nakunst
Head of Regulatory Affairs Europe/USA

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HAMBURG, 04.02.2014

DEPARTMENT Regulatory Affairs Europe
CB/CB

YOUR REFERENCE: DATED:

TELEPHONE-DIRECT-NO.: +49-40/2375-
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## LETTER OF AUTHORIZATION

### Tribenuron-methyl

We, HELM AG, Nordkanalstraße 28, 20097 Hamburg, Germany hereby authorise the Authorities in France to access the following proprietary data held on the active substance Tribenuron-methyl belonging to HELM AG (hereinafter referred to as Proprietary Data) in order to grant the registration of the following product:

| | |
|---|---|
| **Registration holder** | Rotam Agrochemical Europe Ltd<br>Camrascan House, Minerva Business Park,<br>Peterborough<br>PE2 6QR<br>UK |
| **Product** | Dossier: 2012-1169<br>Date de la demande de compléments : 06/11/2013 |
| | Product code: FH-045<br>Product name: Nautius<br>Formulation type: WG<br>Composition: 400 g/kg thifensulfuron-methyl and 150 g/kg tribenuron-methyl |
| **Study/Studies** | dRR Part B, Section 5, IIIA1 9.6, including Appendix 3 and Appendix 4 |

1. The right of referral to the Proprietary Data is only valid in support of the above registration in France. The use of the registration obtained thanks to this letter of access is limited to Agricultural Uses in France.
2. The right of referral is expressly limited to the Annex III studies mentioned above. No access to any further studies is granted by this letter of access.
3. The right of referral is subject to the equivalence of the Tribenuron-methyl used as active substance in the above mentioned Product to the Tribenuron-methyl within the meaning of Annex I of Council Directive 91/414/EEC (including the conditions defined and laid down in the Annex I Review Process). The right of referral is furthermore subject to the fulfilling by ROTAM of all other registration requirements.
4. The right of referral to the Proprietary Data is neither transferable nor sub-licensable to any further companies or other legal or natural entities or its employees, advisors or customers. The right of referral expires in case of transferral of the above mentioned Registration to a new Registration holder.
5. The right of referral applies only to the above mentioned Product and the registered uses and must not be used for any other application, registration extension or amendment without the express written confirmation of HELM AG.
6. ROTAM or any of its affiliates, its employees, its advisors or its customers are not authorized to receive any copies of the Proprietary Data nor are they authorized to inspect or view the Proprietary Data or any specific document in whole or in part, provided this is consistent with the laws of the territory concerned.
7. This letter of access is valid until this permission is withdrawn by HELM AG in writing at any time.

HELM AG, Nordkanalstraße 28, 20097 Hamburg, Germany

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Dr. Diana Nakunst
Head of Regulatory Affairs Europe/USA