Environmental Assessment

1. Date: December 7, 2021

2. Name of Notifier:

SNF SA
ZAC de Milieux
42163 Andrezieux
France

3. Address:

All communications on this matter are to be sent to:
Naeem Mady
Intertek
938 Clint Moore Road
Boca Raton, FL 33487
Telephone: (201) 952-8110
Email: Naeem.mady@intertek.com

4. Description of the Proposed Action

a. Requested Action

The purpose of this food contact notification (FCN) is to seek clearance for the use of SNF's food contact substance (FCS), 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1 yl)amino]-, sodium salt (1:1), polymer with 2-propenamide, reaction products with glyoxal (CAS Reg. No. 2614959-08-7). Although the glyoxalated cationic polyacrylamide resin, as a result of the paper and paperboard manufacturing processes, will remain substantively incorporated into and as a component of finished paper and paperboard through use and disposal activities, the FCS contains residual water-soluble monomers which are not substantive and are, therefore, not incorporated into the finished paper or paperboard, but instead, will be lost during the sheet forming operations at paper mills.

b. Need for action

The FCS is applied prior to the sheet-forming operation at a maximum concentration of 1% by weight of dry fibers in the finished paper or paperboard. It is intended to increase both the dry and wet strength of paper and paperboard. Paper products treated with the FCS are intended for use in contact with all foods under FDA's Conditions of Use (A-H) as prescribed at 21 CFR 176.170 (c), Table 2.[1]

c. Locations of use/disposal

It should be noted that the FCN submitter is not a manufacturer of paper and/or paperboard. Rather, the FCN submitter intends to manufacture and sell the FCS to paper and paperboard manufacturers that will employ the FCS as an additive at the wet end of the paper and paperboard manufacturing processes. The FCS is retained by (adsorbed onto) the paper

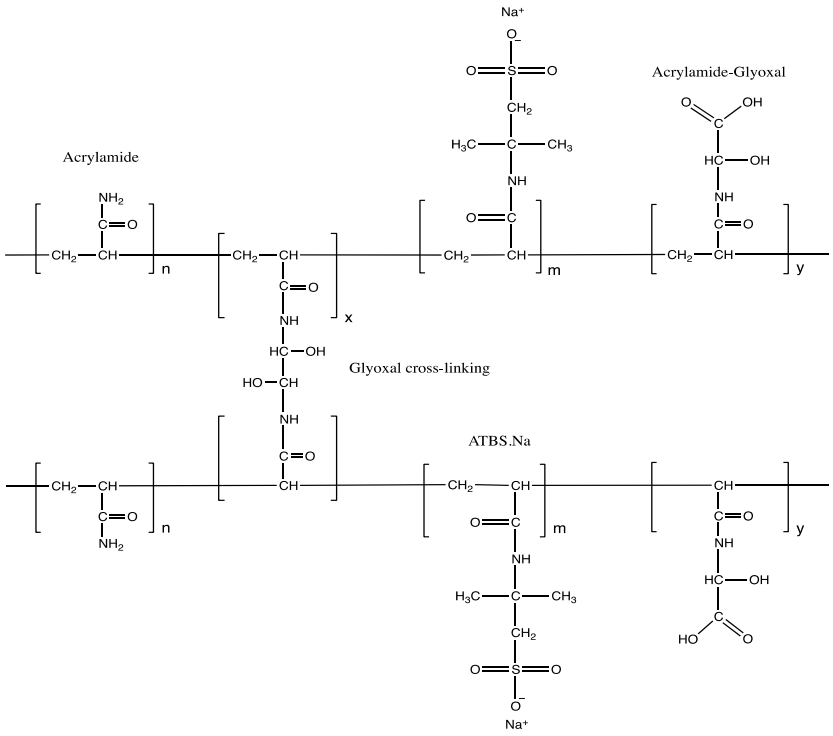
[1] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

fibers during paper production and remains so up through the use and disposal of the finished paper and paperboard. The polymer component comprises less than 1% of the finished food contact article.

Food-contact paper and paperboard products made with paper containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal of such products will occur nationwide, with approximately 20.8% of the materials being recycled and the rest ultimately being deposited in land disposal sites or being incinerated (U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: Facts and Figures 2018).[2] The types of environments present at and adjacent to the disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact paper prepared using the FCS.

5. Identification of Substance that Is the Subject of the Proposed Action

The food contact substance is 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-yl)amino]-, sodium salt (1:1), polymer with 2-propenamide, reaction products with glyoxal (CAS Reg. No. 2614959-08-7).



[2] US EPA Report: *Advancing Sustainable Materials Management*: 2018 Tables and Figures Assessing Trends in Material Generation and Management in the United States. December 2020. Table 5 – Paper and Paperboard in MSA, (Subtotal Containers and Packaging excluding Corrugated Boxes.) https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf

Maximum Level of Impurities in the FCS			
Monomer	***CASRN***	**ppm**	**% (w/w)**
Acrylamide (2-propenamide)	**79-06-1**	**1,000**	**0.1**
ATBS.Na (sodium 2-acrylamido-2-methylpropane-sulfonate)	**5165-97-9**	**2,000**	**0.2**
Glyoxal (ethanedial)	**107-22-2**	**10,000**	**1.0**

6. Introduction of Substances into the Environment

a. Introduction of the substance into the environment as a result of manufacture

Under 21 CFR § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA regulated articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any significant adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. Introduction of the substance into the environment as a result of use/disposal

Paper processors are among those industries required by EPA to meet industry specific effluent pretreatment standards.[3] Therefore, the waste process water containing the FCS and the residual monomers present with the FCS are expected to be disposed of through the processing plant's onsite wastewater treatment facility before discharge either to surface waters under National Pollution Discharge Elimination System (NPDES) permitting or to a publicly-owned treatment works (POTW).

The FCS will be introduced into paper and paperboard manufacturing processes prior to the sheet-forming stage. The FCS will be supplied to paper mills as an aqueous solution (7.5% w/w) and will be dosed into the wet-end of the paper and paperboard manufacturing process at a rate of 1.0% by weight of dry fibers in the finished paper and paperboard. The FCS is designed to become totally incorporated and remain bound within the finished paper and paperboard. The potential of the paper slurry to retain the FCS is, in fact, much higher than the currently solicited use rate. Consequently, the Notifier does not expect that significant concentrations of the FCS will be released to the environment from the paper mills at which the FCS will be used in food contact paper and paperboard manufacturing operations.

[3] See https://www3.epa.gov/npdes/pubs/pretreatment_program_intro_2011.pdf and see table of regulated industries at http://www.epa.gov/eg/industrial-effluent-guidelines

The residual monomers, namely acrylamide, glyoxal, and ATBS.Na, are not expected to be retained by the paper and are expected to become components in the paper mill whitewater that will be sent to the on-site wastewater treatment facilities at paper mills.

The Environmental Introduction Concentrations (EICs) and Expected Environmental Concentrations (EECs) of the residual monomers can be calculated based on the following 'worst-case' assumptions:

• Maximum use level of 10 kg of FCS per metric ton (MT) of dry paper/board which translates to 133.3 kg of FCS based on an active concentration of 7.5% FCS as supplied (10 kg dosed ÷ 7.5% FCS = 133.3 kg),

• 100 cubic meters wastewater is generated per metric ton finished paper/paperboard[4], and

• A 10-fold dilution of the wastewater containing the residual monomers occurs following on-site treatment at the paper mill at the time the treated wastewater is discharged to surface waters.[5]

Based on the above conservative assumptions, the EIC and EEC of each of the 3 residual monomers can be calculated as follows and are as shown below:

$$\text{EIC (ppb)} = Conc.in\ product\left(\frac{mg}{kg}\right) \text{ X dosage}\left(\frac{kg}{MT\ dry\ paper}\right) \text{ X } \frac{1\ MT\ dry\ paper}{100\ m3\ wastewater} \text{ X } \frac{1\ m3\ water}{1000\ kg\ water} \text{ X } \frac{1000\ ppb}{1\ ppm}$$

$$\text{EEC (ppb)} = \text{EIC} * 0.1$$

Residual monomer	Concentration in Product (mg/kg)	Dosage (kg/MT dry paper)	EIC (ppb)	EEC (ppb)	EEC (ppm)
Acrylamide (79-06-1)	1,000	133	1,330	133.0	0.13
ATBS.Na (5165-97-9)	2,000	133	2,660	266.0	0.26
Glyoxal (107-22-2)	10,000	133	13,300	1,330	1.33

Because water is required for many purposes in a paper mill other than carrying pulp and additives, the estimated worst-case EICs for this proposed use of the FCS would be less than the amount estimated above. Although cooling water generated at paper mills may be discharged separately, cleaning and pulping water would be treated along with the white water

[4] The value of 100 cubic meters wastewater is a calculation of wastewater to be treated. Since the concentration of the pulp in the headbox is 1% v/v, there is 100 times more water than pulp.

[5] Rapaport, R.A., 1988. Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution. Environmental Toxicology and Chemistry 7:107-115.

at an onsite wastewater treatment facility prior to release to the POTW or to surface water. A mill dependent dilution factor may also be applied here depending on the types of operations employed at the mill, e.g., the extent of water recycling that is performed, and whether the mill employs a pulping operation.

Additionally, as the subject FCS is intended to compete with, and replace, other acrylamide/glyoxal copolymers already authorized for use as dry and wet strength additives in the manufacture of food contact paper and paperboard, no new environmental introductions of acrylamide or glyoxal are expected as a result of this notification becoming effective.

Solid Wastes

Solid wastes, including disposal by users of paper products generated with the FCS, are expected to be disposed of by either landfill or incineration. The residual monomers are not expected to be present in finished paper and paperboard.

Landfill

In light of EPA's regulations governing municipal solid waste landfills, only extremely small amounts, if any, of the FCS is expected to enter the environment as a result of the landfill disposal of finished articles containing the FCS. EPA's regulations require new municipal solid waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have groundwater monitoring systems. (40 C.F.R. Part 258). Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

Combustion

The food contact substance consists of carbon, hydrogen, nitrogen, sulfur, sodium and oxygen, elements commonly found in municipal solid waste.

To calculate the potential environmental introduction of the FCS due to combustion of finished articles, we have assumed that available carbon in the FCS would be converted to carbon dioxide, that available nitrogen will be converted to nitrous oxide, and assumed that 100% of the market volume will be combusted.

There is the potential for greenhouse gas (GHG) emissions to result from the use and disposal of the FCS during the incineration of articles containing the FCS in MSW combustion facilities. Such facilities are regulated by the EPA under 40 C.F.R. Part 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 C.F.R. § 98.2), describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton CO2-e emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 C.F.R. § 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 C.F.R. § 1508.27(b)(10) states that when evaluating intensity of an impact, one should consider "whether the action threatens a violation of Federal, State, or local law or requirements imposed for the

protection of the environment."

Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as calculated and shown in the confidential attachment to the EA, are below 25,000 metric tons on an annual basis. Thus, as the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

7. Fate of Emitted Substances in the Environment

a. Physical/Chemical properties

Physical and chemical properties[6]				
		Acrylamide	**ATBS.Na**	**Glyoxal**
Log Pow		-0.67	-4.34[7]	-1.66
Water solubility		6.4 x 10^5 mg/L	1 x 10^6 mg/L[7]	1 x 10^6 mg/L
Vapor pressure		0.007 mm Hg	7.4 x 10^{-9} Pa[7]	255 mg Hg
Environmental fate and pathways				
		Acrylamide	**ATBS.Na**	**Glyoxal**
Henry's Law constant	atm-m^3/mol	1E-009[8]	5.2E-015[8]	3.33E-009[8]
Koc	L/kg	0.195[9]	10[10]	2.1[11]
BCF	—	<1[9]	3.16[12]	3.2[12]
Biodegradation in 28 days	%	>70[13]	<10^7 (44 days)	>70[11]

[6] https://chem.nlm.nih.gov/chemidplus/

[7] *European Chemicals Bureau*, EU/OECD Risk Assessment Report ATBS.Na, https://echa.europa.eu/registration-dossier/-/registered-dossier/15188/4/9

[8] HENRYWIN v3.20 EPA

[9] *European Chemicals Bureau*, EU/OECD Risk Assessment Report acrylamide, https://echa.europa.eu/documents/10162/50218bf9-ba0f-4254-a0d9-d577a5504ca7

[10] KOCWIN MCI method

[11] OECD SIDS Document for Glyoxal (CAS No. 107-22-2). UNEP Publications. *Available at* https://hpvchemicals.oecd.org/UI/handler.axd?id=807cc37b-0f54-4005-873a-bf963c2c59e1

[12] BCFBAFv.3.01 EPA

[13] *United States Testing Co., Inc.* Modified OECD Test (Wang, Feb. 20, 1991)

b. Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the subject FCS. The subject FCS is transported and fed via closed systems. This eliminates any possible environmental introductions during these periods. Further, no significant environmental inductions were identified above as a result of combustion of paper and paperboard manufactured with the FCS. In regard to the residual monomers, the Henry's Law constant for the residual monomers indicates that they do not volatilize easily from aqueous solutions such as SNF's formulated product or paper mill process water. In addition, due to their low vapor pressures and high water solubility, the movement of these monomers into the atmosphere is not anticipated. Therefore, no significant quantities of any substances will be release to the atmosphere upon the manufacture, use and disposal of finished articles manufactured with the FCS.

c. Land

As described above, articles manufactured with the FCS are expected to be either land-disposed or incinerated as municipal solid waste. These mechanisms of disposal are managed by local, state and federal regulations. Thus, no significant quantities of any substances will be released into the atmospheric, terrestrial or freshwater, estuarine or marine ecosystems upon the use and proper disposal of food-contact articles manufactured with the FCS.

d. Water

The FCS is incorporated into and is retained in the finished paper and paperboard. Therefore, no significant effect on the concentrations of and exposure to the FCS in water or wastewater treatment sludges are anticipated due to the proposed production, use, and disposal. The residual monomers are very soluble in water and their presence in wastewater is anticipated.

Acrylamide

Acrylamide is expected to be quickly degraded in water by biological processes (Abdelmagid 1982; EPA 2006c; Haberman 2002; WHO 2003 in Toxicological Profile for Acrylamide, US Dept. of Health and Human Services, Agency for Toxic Substances and Disease Registry, Dec.2012).[14] Additionally, acrylamide is not expected to significantly bioconcentrate in aquatic organisms due to its high water solubility and its ability to be degraded by microorganisms (EPA 2006c; Haberman 2002; WHO 2003).[15]

ATBS.Na

The test substance showed a low biodegradation rate of less than 10% after 44 days. The sodium salt of ATBS was not considered to be readily biodegradable.[16] It is expected to have high persistence and low bioaccumulation potential.

ATSB Na displays very low acute toxicity to fish, algae and invertebrates and anticipated environmental exposure levels are orders of magnitude lower than the threshold for acute health

[14] In Toxicological Profile for Acrylamide, US Dept. of Health and Human Services, Agency for Toxic Substances and Disease Registry, Dec. 2012. https://www.atsdr.cdc.gov/toxprofiles/tp203.pdf

[15] Ibid.

[16] https://echa.europa.eu/registration-dossier/-/registered-dossier/15188/4/9

effects to aquatic organisms (see next section). Despite its high persistence, it has low bioaccumulation potential and would not be anticipated to lead to adverse effects during the (relatively short) lifespans displayed by these aquatic organisms.

Glyoxal

Glyoxal is very soluble in water and partitions well between soil organic carbon and water. Therefore, soil and water are the predominant target compartments for glyoxal. However, glyoxal rapidly decomposes photolytically. Its decomposition is also catalyzed by hydroxyl radicals and hydroxide ions. Biodegradation tests indicate that glyoxal also is readily biodegradable in both soil and water and would therefore not be expected to persist or to accumulate above background levels. Because glyoxal is endogenously produced during normal cellular metabolism by a multitude of enzyme independent pathways, there also exist a large number of microbial enzymes that catalyze the transformation of glyoxal to common intermediates in microbial catabolism.[17]

8. Environmental Effects of Released Substances

Acrylamide

According to the SIDS data package for acrylamide[18] the lowest 96-hour LC50 reported for fish is 100 mg/l (*Lepomis macrochirus*); the lowest 48-hour EC50 for invertebrates is 98 mg/l (*Daphnia magna*); and the lowest 72-hour EC50 for algal growth inhibition is 33.85 mg/l (*Selenastrum capricornutum*) (based upon a 72-hour EC50 of 67.7 mg/l for a 50% acrylamide solution). The calculated acrylamide EEC (0.13 ppm) is several orders of magnitude lower than these ecotoxicity endpoints. Therefore, no significant environmental impact is anticipated.

ATBS.Na

According to the ECHA registration data[19] for the sodium salt of ATBS, the lowest LC50 reported for fish is for *Lepomis macrochirus* at 96 hours, the highest test concentration of 1000 mg/l. For invertebrates, there was no effect on *Daphnia magna* at the highest test concentration of 1000 mg/l, and for algae, no inhibition of algal growth or biomass were seen at the single test concentration of 2000 mg/l. The calculated ATBS.Na EEC (0.26 ppm) is several orders of magnitude lower than these ecotoxicity endpoints. Therefore, no significant environmental impact is anticipated.

Glyoxal

According to the SIDS data package for glyoxal[20] the lowest LC50 (96-hour) reported for fish is 215 mg/l (*Pimephales promelas*); the lowest EC50 (48-hour) for invertebrates is 404 mg/l (*Daphnia magna*); the lowest EC50 (96-hour) for algal growth inhibition is greater than 500 mg/l (*Scenedesmus subspicatus*).

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[17] European Commission. Health & Consumer Protection Directorate – General. Directorate C – Public Health and Risk Assessment. C7 – Risk Assessment. Scientific Committee on Consumer Products (SCCP) Opinion on Glyoxal (Adopted during the 4th plenary of June 21, 2005) (SCCP/0881/05)

[18] SIDS Initial Assessment Profile – Acrylamide: http://webnet.oecd.org/Hpv/ui/handler.axd?id=c81f3f95-e5f8-4857-91af-4c76b9094edb

[19] https://echa.europa.eu/registration-dossier/-/registered-dossier/15188/4/9

[20] OECD SIDS Document for Glyoxal (CAS No. 107-22-2). UNEP Publications. *Available at* https://hpvchemicals.oecd.org/UI/handler.axd?id=807cc37b-0f54-4005-873a-bf963c2c59e1

As discussed in Section 7 above, the maximum concentration at which the glyoxal is expected to enter the environment (EEC) can be estimated to be just above 1 ppm. The minimum measure of toxicity presented in the paragraph above, the 96-hour LC50 for *Pimephales promelas*, is 215 mg/l. Thus, there exists an approximate 200-fold margin of exposure, even before accounting for biotic and abiotic depletion mechanisms.

Due to the very low expected environmental concentration, and the fact that cellular organisms have very efficient enzymatic processes for metabolizing glyoxal, it may be concluded that production and use of the FCS will not lead to adverse environmental effects.

Most Sensitive LC/EC 50		
Monomer/EEC	**Result**	**Endpoint**
Acrylamide/0.13 ppm	33.85 mg/L	$EC50_{growth\ inhibition}$/ *Selenastrum capricornutum*/72 hours
Glyoxal/1.33 ppm	215 mg/L	LC50/ *Pimephales promelas* /96 hours
ATBS.Na/ 0.26 ppm	1000 mg/L	LC50 / *Lepomis macrochirus* / 96 hours

9. Use of Resources and Energy

The notified use of the FCS is not expected to result in a net increase in the use of energy and resources, as the FCS is intended to be used in place of similar products now on the market.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of the subject FCS or the food contact paper and board. Therefore, use of the FCS would not be expected to result in any environmental impacts requiring mitigation measure of any kind.

11. Alternatives to the Proposed Action

No significant adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this Notification. The alternative of not clearing the action proposed herein would simply result in the continued use of the materials which the subject FCS would otherwise replace; such action would have no significant environmental impact.

12. List of Preparers

Naeem Mady, M.Sc.

VP of Regulatory Market Access, *Food Contact and Regulatory Services,* Intertek Health, Environmental and Regulatory Services. With an educational background in Chemistry, Naeem has over 30 years of experience in chemical, health and regulatory consulting.

13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: December 7, 2021

Naeem Mady
VP, Regulatory Market Access
Health, Environmental & Regulatory Services
Intertek

14. References

US FDA: Food Types & Conditions of Use for Food Contact Substances
https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

US EPA Report: Advancing Sustainable Materials Management: 2018 Tables and Figures Assessing Trends in Material Generation and Management in the United States. December 2020.
https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf

https://www3.epa.gov/npdes/pubs/pretreatment_program_intro_2011.pdf and see table of regulated industries at http://www.epa.gov/eg/industrial-effluent-guidelines

Rapaport, R.A., 1988. Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution. Environmental Toxicology and Chemistry 7:107-115.

https://chem.nlm.nih.gov/chemidplus/

European Chemicals Bureau, EU/OECD Risk Assessment Report for ATBS.Na,
https://echa.europa.eu/registration-dossier/-/registered-dossier/15188/4/9

European Chemicals Bureau, EU/OECD Risk Assessment Report for acrylamide,
https://echa.europa.eu/documents/10162/50218bf9-ba0f-4254-a0d9-d577a5504ca7

OECD SIDS Document for Glyoxal (CAS No. 107-22-2). UNEP Publications. Available at
https://hpvchemicals.oecd.org/UI/handler.axd?id=807cc37b-0f54-4005-873a-bf963c2c59e1

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In Toxicological Profile for Acrylamide, US Dept. of Health and Human Services, Agency for Toxic Substances and Disease Registry, Dec. 2012.
https://www.atsdr.cdc.gov/toxprofiles/tp203.pdf

European Commission. Health & Consumer Protection Directorate – General. Directorate C – Public Health and Risk Assessment. C7 – Risk Assessment. Scientific Committee on Consumer Products (SCCP) Opinion on Glyoxal (Adopted during the 4th plenary of June 21, 2005) (SCCP/0881/05)

SIDS Initial Assessment Profile – Acrylamide:
http://webnet.oecd.org/Hpv/ui/handler.axd?id=c81f3f95-e5f8-4857-91af-4c76b9094edb

15. Attachment

Confidential Attachment to the Environmental Assessment: Estimate of Greenhouse Gas Emissions from Combustion.