FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: **CHR/F/PYRA 250 EC**

Product name(s): **Etiuda 250 EC, Fermata 250 EC**

Chemical active substance:

Pyraclostrobin, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Innvigo Sp. z o.o.

Submission date: October 2021

MS Finalisation date: 15/12/2022

Version history

When	What
December 2021	Dossier sent for evaluation
September 2022	zRMS evaluation of dRR
December 2022	Final version prepared by zRMS after Commenting period

Table of Contents

zRMS comments:
The text highlighted in grey was provided by the evaluator.

0 Product background, regulatory context and GAP information

0.1 Introduction

This document describes the acceptable use conditions required for zonal registration of CHR/F/PYRA 250 EC (Etiuda 250 EC, Fermata 250 EC) containing ~~clethodim~~ pyraclostrobin in POLAND (ZRMS).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 0-10 and Part C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required by the EU review. It also includes assessment of data and information relating to CHR/F/PYRA 250 EC where that data has not been considered in the EU review. Otherwise assessments for the safe use of CHR/F/PYRA 250 EC have been made using endpoints agreed in the EU review of pyraclostrobin.

This document describes the specific conditions of use and labelling required for the registration of (Etiuda 250 EC, Fermata 250 EC), product code CHR/F/PYRA 250 EC.

0.1.1 Reason for application

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

In addition to the submission of studies as listed in section(s) B01-B10, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Central zone	Poland CHR/F/PYRA 250 EC Etiuda 250 EC, Fermata 250 EC	N/A

0.1.3 Regulatory history of the active(s)

0.1.3.1 Pyraclostrobin

Table 0.1-2: Summary of regulatory history of CAS No: 175013-18-0

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2004/30/EC of 10 March 2004
RMS	DE
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/06/2004
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31/01/2022~~-~~23

Status	
Date of final Commission (re-registration) deadline (Step 2)	31/01/2022~~-~~23
Current expiration of approval	31/01/2022~~-~~23
Low risk substance or Candidate for Substitution?	N/A

On the basis of the proposed and supported uses, the following particular issues have been identified as requiring particular and short term (within 12 months at the latest) attention from the Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:
- Member States should pay particular attention to the protection of aquatic organisms, especially fish.
- Member States should pay particular attention to the protection of terrestrial arthropods and earthworms.
Risk mitigation measure should be applied, if appropriate.

The SANCO report for pyraclostrobin (SANCO/1420/2001-Final – 8 S~~s~~eptember 2004) is considered to provide the relevant information on the evaluation or a reference to where such information can be found.

Table 0.1-3: Information on minimum purity of Pyraclostrobin

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
975 g/kg	For the purity of active substance, please refer to PART C- confidantial information Equivalence report available: Y

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).
**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised.

0.2 zRMS conclusion

Section 1, 2 and 4. Identity, physical and chemical properties and further information
Based on accepted two-year study the shelf-life of two years can be granted for the PPP.
Based on physicochemical properties the PPP is not classified.

Section 3. Efficacy
The evaluation of the application of CHR/F/PYRA 250 EC resulted in the decision to grant authorization for use according to the GAP table.

Section 5. Analytical Methods
The analytical method used for analysing active substance in in the plant protection product meets the SANCO/3030/99 rev. 5.

Section 6. Mammalian Toxicology
Classification of CHR/F/PYRA 250 EC: Skin Irrit.2 (H315), Eye Dam. 1 (H318), Acute Tox. 4 (INH).
Operator: Drift reduction, workwear during mixing/loading and application step. Due to the hazard characterisation – protective clothes, protective gloves and face/eye protection at the mixing/loading step and handling.
Worker: (Protective) clothes and gloves.
Residents and Bystanders: Warning signs, drift reduction, 5 meter buffer strip.

Section 7. Metabolism and Residues

This application is in support of the use of CHR/F/PYRA 250 EC containing 250 g/L pyraclostrobin on wheat, triticale, barley and rye in Poland.

Critical GAP proposed for CHR/F/PYRA 250 EC on winter wheat, winter triticale and winter/spring rye: BBCH 25-69, max. 2 applications, min. interval between applications 21 days, max. applica-tion rate per application 0.25 kg a.s./ha, PHI-35 days.
Critical GAP proposed for CHR/F/PYRA 250 EC on spring barley: BBCH 25-59, max. 2 applica-tions, min. interval between applications 21 days, max. application rate per application 0.25 kg a.s./ha, PHI-35 days.

Critical EU GAP on wheat and rye (art 12, EFSA Journal 2011;9(8):2344): formulation WG, max BBCH 69, max. 2 applications, max. application rate 0.25 kg a.s./ha, PHI-35 days.
Critical EU GAP on barley (art 12, EFSA Journal 2011;9(8):2344): formulation WG, max BBCH 61, max. 2 applications, max. application rate 0.25 kg a.s./ha, PHI-35 days.
The GAPs proposed for CHR/F/PYRA 250 EC are covered by GAPs evaluated at EU level.

Stability

The Applicant did not submit any new stability studies for pyraclostrobin residues.
According to the EFSA Journal 2011;9(8):2344: The demonstrated storage stability of pyra-clostrobin in treated crops was evaluated under the peer review of Directive 91/414/EEC (Germany, 2001). Studies demonstrated storage stability of pyraclostrobin in high oil con-tent, high water content, acidic and dry commodities for up to 18 months when stored deep frozen.
The storage stability of pyraclostrobin in animal products was evaluated under the peer review of Directive 91/414/EEC (Germany, 2001). Studies demonstrated storage stability of pyraclostrobin in milk and animal tissues for up to 8 months when stored deep frozen. No storage stability study was performed on poultry eggs.

Nature of residues in plants

The Applicant did not submit any new metabolism studies.
According to the EFSA Journal 2011;9(8):2344:
Metabolism of pyraclostrobin was investigated for foliar applications on cereals (wheat), on fruits and fruiting vegetables (grapes) and on root and tuber vegetables (potatoes) using [tolyl-U-14C]-pyraclostrobin and [chlorophenyl-U-14C]- pyraclostrobin (Germany, 2001). Generally it was concluded in the peer review (EC, 2002) that the metabolic pathway is similar in all crop groups investi-gated. Results from the supervised residue trials indicated that desmethoxy metabolite 500M07 occurs in crops in small amounts compared to parent pyra-clostrobin; therefore in the peer review it was concluded that a general residue definition for risk assessment and enforcement should be set as parent pyraclostrobin only.
In the peer review the metabolism of pyraclostrobin in rotational crops was studied in lettuce, rad-ish and wheat with [tolyl-U-14C]-pyraclostrobin and [chlorophenyl-U-14C]-pyraclostrobin (Germany, 2001). The radiolabelled active substance was applied on a bare soil once at an application rate of 0.9 kg a.s./ha and respective crops were sown or planted at 30, 120 and 365 DAT. The peer review concluded that the metabolic pathway of pyraclostrobin in rotational crops is similar to that in primary crops and no formation of new metabolites was observed. There is no accumulation of pyraclostrobin or its degradation products (including 500M07) in the parts of plants used for human or animal con-sumption. The relevant residue in rotational crops therefore should be defined as parent pyraclostrobin.

The total radioactive residues in the edible parts of succeeding crops were very low for all plant back intervals: radish roots, lettuce ≤ 0.04 mg/kg and wheat grain ≤0.089 mg/kg. No accumula-tion of pyraclostrobin or its residues was observed in rotational crops. Application rates sup-ported in the framework of this review range between 0.05 and 0.67 kg a.s./ha. Considering the overdosing factor of the above study and the fact that pyraclostrobin was applied to a bare soil (interception of pyra-clostrobin by the plants is expected in practice), it is expected that residues of pyraclostrobin re-sulting from soil uptake will not exceed 0.01 mg/kg. Specific plant-back restrictions related to the use of pyraclostrobin are therefore not required, provided that py-raclostrobin is applied in compliance with the GAPs evaluated in the framework of this review.
The effect of processing on the nature of pyraclostrobin residues was investigated in the framework of the peer review. A study was conducted simulating representative hydrolytic condi-tions forpas-teurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C pH 5) and sterilisation (20 minutes at 120°C, pH 6). This study demonstrates that food processes such as brewing, cooking, sterilisation or pasteurisation, will not impact on the nature of pyraclostrobin residues. The relevant residue for enforcement and risk as-sessment in processed commodities is therefore expected to be the same as for primary crops.

Nature of residues in livestock
The Applicant did not submit any new metabolism studies.
According to the EFSA Journal 2011;9(8):2344:
The nature of pyraclostrobin residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (Germany, 2001). Reported metabolism studies in-clude 4 studies, two in lactating goats and two in laying hens using 14C-chlorophenyl la-beled pyra-clostrobin and 14C-tolyl labeled pyraclostrobin. Studies of the metabolism of pyra-clostrobin in goats showed that residues in products of animal origin derive from the parent compound as well as from its desmethoxy metabolite (500M07). After five consecutive daily oral administrations of 14C-pyraclostrobin at a nominal dosage of 12 or 50 mg/kg DM feed, there was rapid absorption from the gastrointestinal tract. Radioactivity was excreted mainly via the faeces. The radiolabel in milk accounted for only 0.1–0.5% of the total applied radioactivity. There was no indication of accu-mulation of 14C-pyraclostrobin in tis-sues. The parent compound was found in fat, muscle and, at lower amounts, in liver. Me-tabolites are formed in liver and kidney by hydroxylation of the chlo-rophenyl and tolyl rings and by cleavage of the molecule. Little extraction was seen in liver. Pyraclostrobin was present in all tissues and in milk and was the main residue component in muscle and in fat (log Pow = 3.9) (FAO, 2004). Tissues and eggs from hens that received an exaggerated dose of 0.70 or 0.88 mg/kg bw/d on seven consecutive days contained low residue levels consist-ing of three main metabolites. The parent compound was found in fat and eggs but not in liver. The main me-tabolite in liver was the glucuronic acid conjugate, which was bound to the tolyl ring of the de-methoxylated parent structure. The desmethoxy metabolite (500M07) was also present in fat and eggs. The main metabolite in fat and eggs was 500M07, and that in liver was the glucuronic acid con-jugate (FAO, 2004).
The relevant residue for risk assessment is defined as the sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety, expressed as pyraclostrobin. EFSA proposes to set different levels of conversion factor from enforcement to risk assessment. Conversion factors will be set at 4 for ruminant liver and at 1 for all other commodities. In the framework of the peer review, the pro-posed residue definition was considered to be fat soluble based on the fact that the log Po/w of pyraclostrobin is higher than 3 (Germany, 2001).

The magnitude of residues in plants
The Applicant did not submit any new studies. The available residue trials evaluated in the DAR, 2001 and in EFSA 2011 (art. 12) are considered adequate for the intended uses of CHR/F/PYRA 250 EC. The results of the available residue trials show no residues above the applicable MRLs (1 mg/kg for barley and 0.2 mg/kg for wheat and rye according to the Reg. (EU) 2020/1633).

According to the EFSA Journal 2011;9(8):2344: Studies investigating the magnitude of residues in processed commodities of table and wine grapes, barley and wheat were also reported in the framework of the peer review (Germany, 2001). Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if there would be the intention to derive more robust processing factors, in particular for enforcement purposes, addi-tional processing studies would be required.
The total radioactive residues in the edible parts of succeeding crops were very low for all plant back intervals: radish roots, lettuce ≤ 0.04 mg/kg and wheat grain ≤0.089 mg/kg. No accumulation of pyraclostrobin or its residues was observed in rotational crops. Application rates supported in the framework of this review range between 0.05 and 0.67 kg a.s./ha. Considering the overdosing factor of the above study and the fact that pyraclostrobin was applied to a bare soil (interception of pyraclostrobin by the plants is expected in practice), it is expected that residues of pyraclostrobin resulting from soil uptake will not exceed 0.01 mg/kg. Specific plant-back restrictions related to the use of pyraclostrobin are therefore not required, provided that pyraclostrobin is applied in compli-ance with the GAPs evaluated in the framework of this review.
The max. application rate proposed in the GAP for CHR/F/PYRA 250 EC is the same (0.25 kg a.s./ha), which has already been considered by EFSA. Specific plant-back restrictions related to the use of pyraclostrobin are therefore not required.

Livestock feeding studies
The Applicant did not submit any new studies. According to the EFSA Journal 2011;9(8):2344: During the peer review of Directive 91/414/EEC the magnitude of pyraclostrobin residues in live-stock was investigated in a feeding study with lactating cows (Germany, 2001). Three groups of lactating cows, each consisting of three animals, were dosed for 28 days with pyraclostrobin at levels of 0.22, 0.37 and 2.4 mg pyraclostrobin/kg bw/day. The samples were analyzed for parent pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety.
No residues of pyraclostrobin and its metabolites could be detected in samples of milk from the 1x and 3x levels except for cream samples where residues in the range of 0.02 mg/kg to 0.04 mg/kg occurred. In the exaggerated 10 x dose group, residues up to 0.18 mg/kg were detected in milk, which mainly consisted of hydroxylated metabolites. As expected, the residue concentrations were higher in cream than in milk or skimmed milk, but the concentration was only moderate (Germany, 2001). In fat and muscle, no residues have been detected at any dose level. In kidneys, residues were only found in the 10x group. In liver, the highest residues were found mainly consisting of hydroxylated metabolites. The withdrawal cows (daily dose of 1400 mg/day and animal) showed a rapid decline of residues. After seven days of withdrawal, residues could only be detected in liver (0.5 mg/kg). Therefore, it can be concluded that pyraclostrobin and its metabolites were eliminated rapidly from the animal (Germany, 2001). This livestock feeding study was rejected by JMPR because no resi-dues were found in fat (FAO, 2004). However, under the peer-review, it was concluded that this livestock feeding study was acceptable (EC, 2002).
It is therefore concluded that significant residues in edible matrices of ruminants and pigs are not expected and that MRLs for these commodities can be established at the LOQ.
No livestock feeding study is available for poultry but the metabolism study in laying hens was performed at dose levels of approximately 0.7 and 0.88 mg/kg bw/d, which represents 100 times the calculated dietary intake. When extrapolating residue levels obtained in the metabolism study to the calculated intake, no residues above LOQ are expected in any poultry tissues or eggs.

Taking into account available feeding data, there is no risk for animal MRL to be exceeded.

Consumer risk assessment
The calculations on consumer risk assessment were performed using PRIMo rev. 3.1 for the crop under assessment and animal products, considering the MRLs in force (Reg. (EU) 2020/1633). The CF of 4 for ruminant liver and 6.8 for milk were also included (EFSA 2019:17(7)5797).
The proposed uses of pyraclostrobin in the formulation CHR/F/PYRA 250 EC do not represent unacceptable acute and chronic risks for the consumer.

There are sufficient studies to support the use of the CHR/F/PYRA 250 EC applied according to the proposed GAPs in Poland on wheat, barley, triticale and rye.

Section 8. Environmental Fate
In accordance with proposed pattern use of CHR/F/PYRA 250 EC, all relevant information was submitted.

Section 9. Ecotoxicology
Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed uses of CHR/F/PYRA 250 EC poses acceptable risk to non-target organisms, if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from CHR/F/PYRA 250 EC applications are required for aquatic organisms.

Section 10. Assessment of the relevance of metabolites in groundwater
No metabolites exceeded trigger value 0.1 µg/L, therefore the relevance assessment of the metabolites is not required.

Uses to be considered safe on the basis of EU methodology:

Uses no. 1-4 and Article 51 use no. 1

Uses to be considered non-safe on the basis of EU methodology:

None

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

Section B9 Ecotoxicology: For FOCUS R4 stream scenario no safe use of CHR/F/PYRA 250 EC was indicated.

Appendix 1 ALL intended uses

GAP rev. , date: 2021-09-02

PPP product name:		Formulation type:	SC [a, b]
product code:	CHR/F/PYRA		
Active substance 1:	piraclostrobin	Conc. of as 1:	250 g/l [c]
Active substance 2:	-	Conc. of as 2:	- [c]
Active substance 3:	-	Conc. of as 3:	-
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	PUH Chemirol Sp. z o.o.	Professional use:	☒
Zone(s):	Central [d]	Non professional use:	☐

Verified by MS: ~~No~~ yes

Field of use: fungicide

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safen-er/synergist per ha [f]	ZRMs Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter-val between applications (days)	kg or L prod-uct / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			

Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat (TRZAW)	F	*Mycosphaerella graminicola, Fusarium avenaceum, Pyrenophora tritici, Puccinia striiformis, Blumeria graminis, Phaeosphaeria nodorum, Puccinia recondita*	Spray, medium sprayer	Spring BBCH 25-69	a) 2 b) 2	21	a) 1 l/ha b) 2 l/ha	a) 0,25 kg a.s./ha b) 0,5 kg a.s/ha	~~100-~~ ~~400~~ 200-300	35		A
2	PL	Winter triticale (TTLWI)	F	*Rhynchosporium secalis, Blumeria graminis, Pyrenophora triticirepentis , Mycosphaerella graminicola, Fusarium avenaceum*	Spray, medium sprayer	Spring BBCH 25-69	a) 2 b) 2	21	a) 1 l/ha b) 2 l/ha	a) 0,25 kg a.s./ha b) 0,5 kg a.s/ha	~~100-~~ ~~400~~ 200-300	35		A
3	PL	Winter rye (SECCW)	F	*Rhynchosporium secalis, Puccinia recondita, Mycosphaerella graminicola, Blumeria graminis*	Spray, medium sprayer	Spring BBCH 25-69	a) 2 b) 2	21	a) 1 l/ha b) 2 l/ha	a) 0,25 kg a.s/ha b) 0,5 kg a.s/ha	~~100-~~ ~~400~~ 200-300	35		A
4	PL	Spring barley (HORVS)	F	*Pyrenophora teres, Blumeria graminis, Rhynchosporium secalis, Cochliobolus sativus, Puccinia hordei*	Spray, medium sprayer	Spring BBCH 25-59	a) 2 b) 2	21	a) 1 l/ha b) 2 l/ha	a) 0,25 kg a.s/ha b) 0,5 kg a.s/ha	~~100-~~ ~~400~~ 200-300	35		A
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
1														
2														

Minor uses according to Article 51 (zonal uses)														
1	PL	Spring Rye (SECCS)	F	*Rhynchosporium secalis, Puccinia recondita, Mycosphaerella graminicola , Blumeria graminis, Phaeosphaeria nodorum*	Spray, medium sprayer	Spring BBCH 25-69	a) 2 b) 2	21	a) 1 l/ha b) 2 l/ha	a) 0,25 kg a.s/ha b) 0,5 kg a.s/ha	~~100-~~ ~~400~~ 200-300	35		A
2														
Minor uses according to Article 51 (interzonal uses)														
1														
2														

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and 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
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3