Minimizing Operator Exposure: Field Data Analysis of Three Closed Transfer Systems (CTS) for pesticide Mixing and Loading

This work has been conducted to support the proposal to include reduction factors for mitigation by CTS to calculations of potential and actual exposure using the AOEM

Date: 25th April 2023

Author: Crop Life Europe (CLE)

Accompanying documents:

1. OPERATOR EXPOSURE STUDY TO EVALUATE THE DERMAL EXPOSURE TO OPERATORS WHEN PERFORMING MIXING/LOADING ACTIVITIES WITH THREE TYPES OF CLOSED TRANSFER SYSTEMS (EASYCONNECT, EASYFLOW M AND GOATTHROAT®). Study code ACI21-001, by Andrew Wilson, final version 02 April 2023.

2. Development and Validation of Analytical Methods for the Determination of Xylitol and Sorbitol in Different OPEX Matrices. Study code S21-09185 by Nicole Heinz. Final version 21 December 2022.

3. Data Summary Table - all matrices

CropLife Europe aisbl | 9 Rue Guimard | 1040 Brussels | Belgium | BE 0447 618 871 Register of Legal Persons
Francophone Section of the Business Court of Brussels | croplifeeurope@croplifeeurope.eu | www.croplifeeurope.eu
Tel: +32 2 663 15 50 | Fax: +32 2 663 15 60

Contents

Background and aims

Contamination of operators when using plant protection products (PPPs) should be as low as possible to ensure their continued approval for use. One way to achieve this is to use personal protective equipment (PPE), like coveralls and gloves. An emerging technology designed to minimize further exposure of operators to PPPs during mixing and loading (M&L) of the spray tank is the use of closed transfer systems (CTS). These are devices that allow neat pesticide mixture to be transferred from its container to the spray tank, thereby resulting in negligible exposure to the operator and the environment. By contrast, open pour practices widely used by famers may leave the farmer and the environment open to significant exposure due to spillage (Figure 1). While there are several CTS types now available, there are only a few field studies, which report the exposure to operators using CTS during M&L of PPPs. Therefore, more data are needed to demonstrate the efficacy of this technology in reducing operator exposure during this process. This will increase confidence of farmers to use CTS routinely, thus resulting in safer pesticide handling. These data can also be used to derive reduction factors for calculating the exposure to PPPs during M&L when using CTS as part of a risk assessment. Therefore, this study was conducted to evaluate the general efficiency of CTS as an exposure mitigation method during M&L. The aim was to achieve a minimum exposure reduction of >90% compared with open-pour data from the Agricultural Operator Exposure Model (AOEM) model (BfR, 2013[1]; Großkopf et al., 2013[2]).

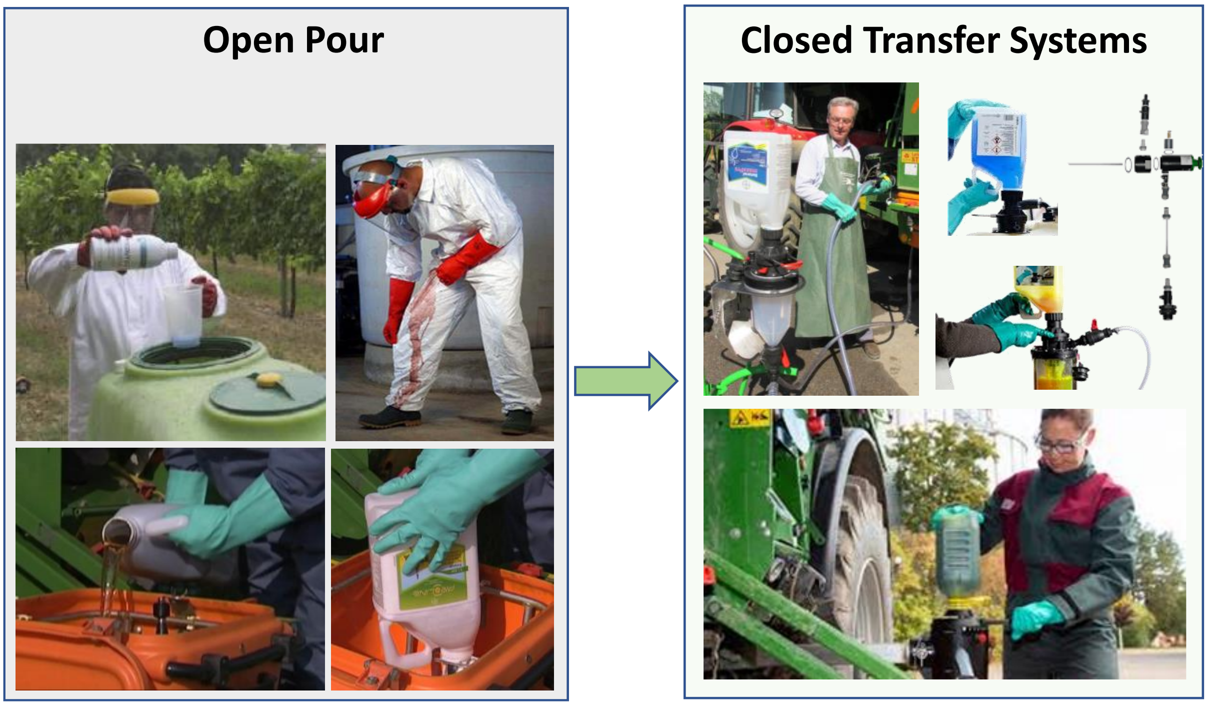

Fig. 1 Photos of farmers using open pour and CTS technology to conduct M&L activities.

[1] BfR. (2013). Bundesinstitut für Risikobewertung. Joint development of a new Agricultural Operator Exposure Model. Project report. Retrieved from [website]: https://www.bfr.bund.de/cm/350/joint-development-of-a-new-agricultural-operator-exposure-model.pdf.

[2] Großkopf, C., Mielke, H., Westphal, D., Erdtmann-Vourliotis, M., Hamey, P., Bouneb, F., Rautmann, D., Stauber, F., Wicke, H., Maasfeld, W., Salazar, J. D., Chester, G., & Martin, S. (2013). A new model for the prediction of agricultural operator exposure during professional application of plant protection products in outdoor crops. Journal für Verbraucherschutz und Lebensmittelsicherheit, 8(3), 143-153. https://doi.org/10.1007/s00003-013-0836-x

CTS types evaluated

The three CTS types evaluated were “easyFlow M”, “easyconnect” and “GoatThroat®”, the choice of which covers the common variability in use amongst farmers, thereby increasing the scientific validity of the study. EasyFlow M (referred to from here as “easyFlow”) and easyconnect are inverted extraction systems (i.e., the bottle is turned upside down) with mechanical rinsing for cleaning (Figure 2). The main difference between easyFlow and easyconnect is how the container is connected to the CTS.

EasyFlow uses an adapter that is screwed on the PPP container to replace the original cap, which means the PPP container must be provided with a foil seal.

The **easyconnect** system consists of two components: a unique cap – which is pre-fitted on the containers – and a coupler, which means the container does not need foil seals. Both systems were specifically designed to mitigate exposure during the filling process of large tanks.

GoatThroat is a probe extraction system with manual rinsing for cleaning (shaking), for which the PPP containers must carry a foil seal. All these CTS types are easy to use and require minimal training.

An overview of all three systems is provided in the following Figure 2.

	easyconnect	easyFlow M	GoatThroat®
System Type	Inverted extraction	Inverted extraction	Probe extraction
Connector (CTS-Container)	Pre-fitted cap	Adapter	Adapter with probe
Container needs foil seal?	No	Yes	Yes
Cleaning process	Mechanical rinsing	Mechanical rinsing	Manual rinsing

Fig. 2 Information on the CTS systems used in the study: easyconnect, easyFlow M, and GoatThroat®

All three systems were tested to ISO 21191 standards. This means they fulfilled the lists three parameters with direct relevance to the operator:

1) no leakage during transfer and rinsing.
2) maximum residue on coupling after disconnection should be <0.25 mL of undiluted product (accumulated over all potential contact surfaces) and
3) the maximum residue in any container rinsed shall not exceed 0.01% of the original content of the container).

Study outline and rationale for specific design aspects

The field part of the fully GLP-compliant whole body dosimetry study was conducted in October and November of 2021 in four European countries. Twelve operators, three per country, were each handling all three CTS systems with two different products. Consequently, a total of 72 dosimeter sets (gloves, hands, head, inner and outer body garment) were collected and subjected to residue analysis. This number of replicates is equivalent to 50-88% of the total replicates used to build the AOEM for M&L (for tanks and M&L of liquids). Operators were actual farmers who undertook the activities (after a brief training session to familiarise themselves with the CTS types) at various sites within Europe (Germany, Spain, France, and the Netherlands) to account for variation of agricultural practices and operator attitude.

One of the two products was an SC (suspension concentrate) formulation containing 212 g/L Xylitol (with a high viscosity of ~472 mPas) in 5 L containers and the other product was an SL (soluble concentrate) containing 920 g/L Sorbitol (with a low viscosity of ~15 mPas) in 10 L container. These were selected rather than real crop protection products for several reasons:

1. they are food grade materials; therefore, they do not raise operator exposure safety concerns and there are fewer problems regarding their disposal at the end of the study compared to active PPP ingredients.
2. Both formulations have a good water solubility, making them easy to use in the test liquid formulations and to modulate the viscosity without the use of additives.

The study focussed on exposure to liquids, which meant that the measurement of inhalation exposure was not needed since respiratory exposure to a pesticide in liquid form is reported to be generally more than one order of magnitude lower than exposure to a pesticide in granular form (Aprea et al., 2016[3]; Knaak et al., 1980[4]).

The number of M&L activities was based on an application to 50 ha, which is representative of a typical working day. The monitored activities were conducted using commercial equipment according to their normal procedures, under the close supervision.

The low and high application rates (0.053 and 4.6 kg a.s./ha) were chosen for the study since these application rates correlate with the rates used in the studies upon which the AOEM was developed.

The study monitored the M&L for two theoretical spray tank volumes (1000 L and 5000 L), which represent the lower and upper range of spray tank volumes in regular commercial use. The theoretical spray volume was 200 L/ha; therefore, each operator performed ten individual mixing events for the 1000 L spray tanks and two individual mixing events for the 5000 L spray tanks. By using these theoretical tank sizes, the requirement for an increased number of partial container emptying (for the lower volume sprayers) with concurrent risk of increased exposure at the CTS/container interfaces was also accounted for.

Dermal exposure to the test item was measured by the operators wearing two layers of whole-body dosimeters to determine potential (naked), actual (one layer of clothing) exposure. The method of analysis was a specific focus, with the aim of achieving a limit of detection (LOD) and limit of quantification (LOQ) which resulted in all the samples with values above these limits. The LOQ and LOD for Xylitol and Sorbitol were the same for each type of sample collected (Table 1). The overall mean procedural recoveries for each matrix and for each analyte were all between 97% and 109%. The RSD ranged between 6% and 11%. Therefore, the analytical efficiency is proven on the days of sample analysis.

[3] Aprea, M. C., Bosi, A., Manara, M., Mazzocchi, B., Pompini, A., Sormani, F., Lunghini, L., & Sciarra, G. (2016). Assessment of exposure to pesticides during mixing/loading and spraying of tomatoes in the open field. J Occup Environ Hyg, 13(6), 476-489. https://doi.org/10.1080/15459624.2016.1143948

[4] Knaak, J. B., Jackson, T., Fredrickson, A. S., Rivera, L., Maddy, K. T., & Akesson, N. B. (1980). Safety effectiveness of closed-transfer, mixing-loading, and application equipment in preventing exposure to pesticides. Arch Environ Contam Toxicol, 9(2), 231-245. https://doi.org/10.1007/bf01055377

Table 1. LOD and LOQ for Xylitol and Sorbitol samples

Sample	LOD	LOQ
Inner dosimeter patches	0.022 µg/100 cm^2 patch	0.1 µg/100 cm^2 patch
Outer dosimeter	0.028 µg/100 cm^2 patch	0.1 µg/100 cm^2 patch
Gloves	0.27 µg/glove	1.0 µg/glove
Gauze pads	0.053 µg per two gauze pads	0.2 µg per two gauze pads
Liquids	0.080 µg/L	0.4 µg/L

To evaluate the reduction in exposure using the three CTS forms, the 75th (chronic) and 95th (acute) centile values for potential and actual from the study were compared with existing data from the AOEM as a benchmark for open pour loading (75^{th} vs 75^{th}, 95^{th} vs 95^{th}). Accordingly, exposure reduction was calculated in % reduction.

Summary of results

Potential exposure reduction using three CTS types

The range, arithmetic mean, geometric mean, and the 75th and 95th centiles for potential exposure to Sorbitol and Xylitol are summarised in Table 2. The distribution of the values of potential exposure to Sorbitol for easyconnect (mean = 13.1 mg/person) and easyFlow (mean = 7.14 mg/person) were not statistically significantly different from each other ($p>0.05$) and could thus be pooled to represent "inverted CTS" types. The same is true for the exposure to Xylitol: easyconnect (mean = 0.268 mg/person) and easyFlow (mean = 0.290 mg/person) were not statistically different from each other ($p>0.05$). By contrast, the distribution of the potential exposures to Sorbitol and Xylitol using the GoatThroat CTS were statistically significantly higher (mean values = 101 and 4.36 mg/person, respectively) from the inverted CTS results ($p<0.01$). Therefore, these data were handled separately in the calculations for exposure reduction.

Table 2. Summary of potential dermal exposure when using easyconnect, easyFlow or GoatThroat® CTS types (mg/operator)

	Analyte	Range Min	Range Max	Arith. Mean	Geo-mean	75th percentile	95th percentile
	easyconnect						
Potential exposure[1]	Sorbitol	1.19	116	13.1	4.11	3.95	59.4
	Xylitol	0.0929	1.02	0.268	0.208	0.298	0.647
	easyFlow M						
Potential exposure[1]	Sorbitol	2.12	18.2	7.14	5.66	10.3	15.4
	Xylitol	0.127	0.599	0.290	0.258	0.324	0.573
	GoatThroat® [2]						
Potential exposure[1]	Sorbitol	41.9	220	101	87.3	118	211
	Xylitol	1.40	12.0	4.36	3.61	4.82	9.18

[1] Calculated from the sum of the residues on all the outer dosimeters, inner dosimeters, face/neck wipes, gloves, and hand wash.
[2] Excluding the results from operator 1 who used a different type of probe (telescopic) from the other eleven operators (fixed length).

The individual operator values for the potential exposure to Sorbitol and Xylitol are shown in Figure 3. The calculated 75th and 95th centiles for Sorbitol (Figure 3A) using the inverted CTS types include the extremely high value measured for Operator 32 (using easyconnect, green bars) who unintentionally unscrewed the connector on the container. Despite this high value, it is still below 10% of the 95th centile of the AOEM. All other values for the inverted CTS type were below 10% of the 75th centile of the AOEM. The handled amount of product containing Xylitol (Figure 3B) by each operator was much lower than for Sorbitol (2.65 kg Xylitol/day compared to 230 kg Sorbitol/day, respectively). Therefore, all values for potential (and actual) exposure of Xylitol are much lower than for Sorbitol. Operator 32 again exhibited a markedly high outlier exposure for Xylitol, which was also the highest measured exposure value for the inverted CTS types. Despite this, all values for actual exposure using the inverted CTS type were below 10% of the 75th centile of the AOEM (Figure 5).

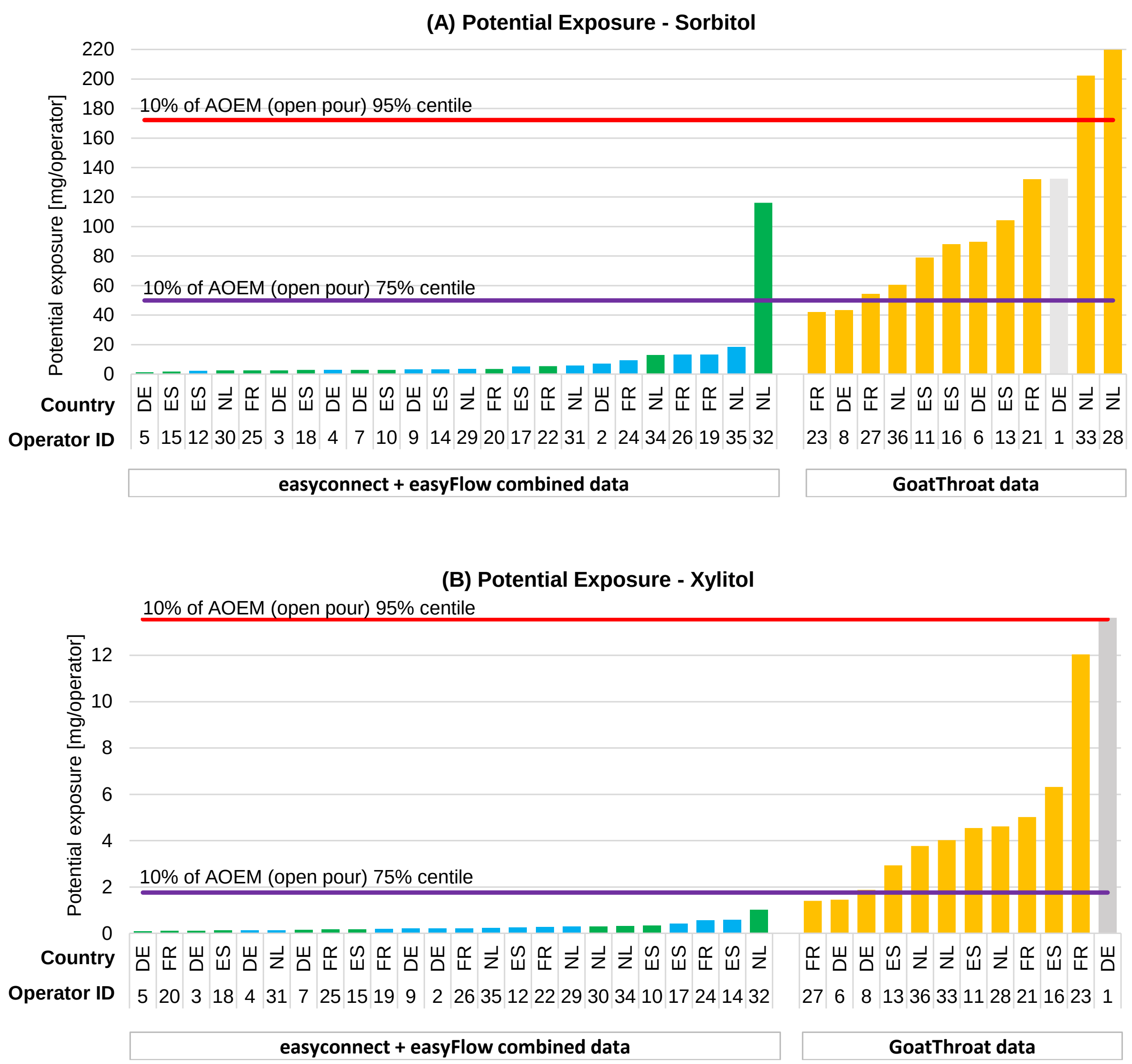

Fig. 3 Individual operator values for the potential exposure to (A) Sorbitol and (B) Xylitol. Green bars denote easyconnect, blue bars denote easyFlow and orange bars denote GoatThroat. The red line denotes 10% of the open-pour AOEM 95th centile and the purple line denotes 10% of the open-pour AOEM 75th centile.

Another notable observation in the study was for Operator 1 (denoted by grey bars in Figure 3), who used the GoatThroat® with a different type of dip tube (telescopic) from the other operators (who used a standard dip tube) (Figure 4). In a reduced ISO evaluation of the three CTS types, samples were taken from standard tube as well as the overlapping part of the telescopic tube after rinsing the container. This revealed that that the rinsing water did not reach the overlapping areas of the telescopic tube, which are only accessible after the telescopic tube was extended again. This led to leakage of the liquid on to the work surface, thus increasing the contamination (denoted by the red borders in the photo in Figure 4). The GoatThroat® system with the telescopic tube does not pass the ISO certification (test 5.2.2) due to excessive residues on the tube (> 100-fold higher than the standard tube), whereas the standard tubes pass this test. While the use of the telescopic tube by Operator 1 did not result in a markedly higher exposure to the low viscosity product, Sorbitol (Figure 3A), this operator did have highest residue measured for the high viscosity product, Xylitol (Figure 3B). This difference is likely to be due to the easy of rinsing low and high viscosity products from the dip tube.

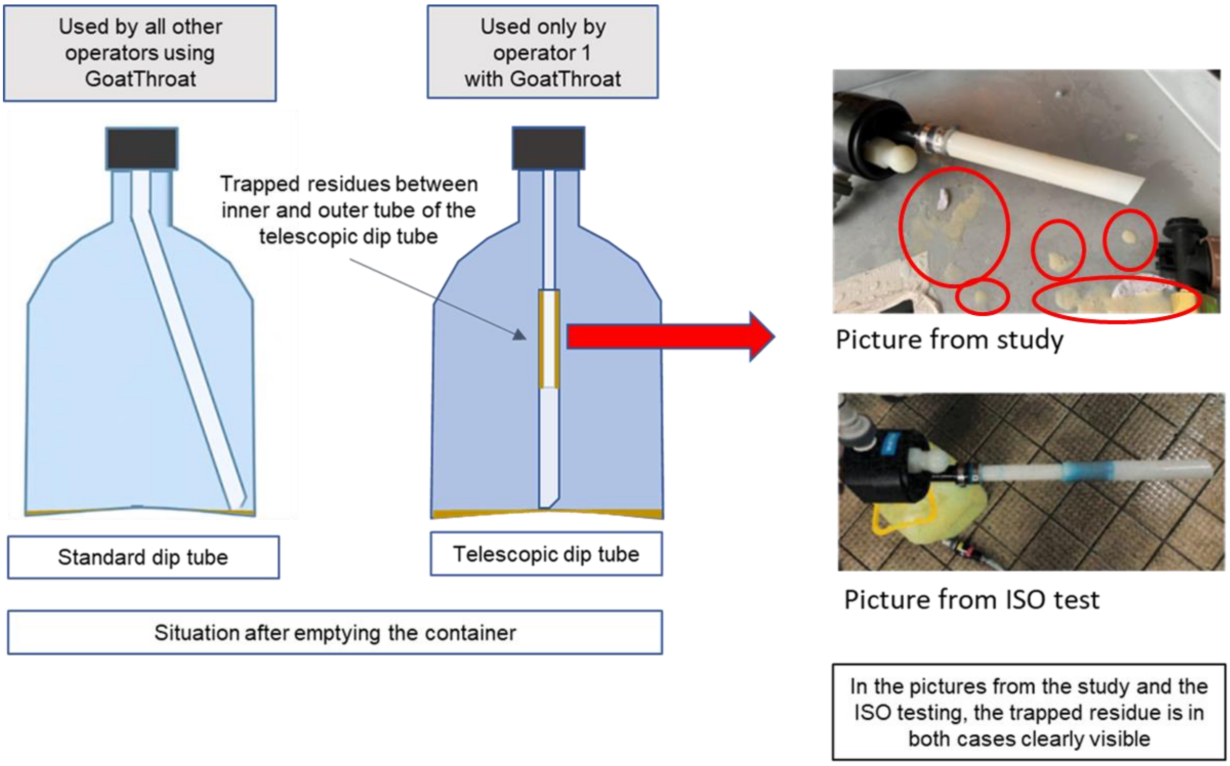

Fig. 4 Representation of the impact of the use of a telescopic dip tube in the GoatThroat® on the recovery of PPP residues

Actual exposure reduction using three CTS types

The range, arithmetic mean, geometric mean, and the 75th and 95th centiles for actual exposure to Sorbitol and Xylitol are summarised in Table 3. There was no statistically significant difference in the actual exposure when using the three CTS types. Indeed, the actual exposure to Sorbitol and Xylitol appeared to be random across the different operators using all three CTS types (Figure 5), with no correlation of the amount on face wipes, hand washes and inner dosimeters with the measured values on the gloves and outer dosimeters. All actual exposure values for Sorbitol (ranging between 0.021 and 0.83 mg/person) were well below the value of 10% of the 75th centile of the AOEM. The Xylitol values ranged between 0.019 and 0.11 mg/person and were below the value of 10% of the 95th centile of the AOEM.

Table 3. Summary of actual dermal exposure when using easyconnect, easyFlow or GoatThroat® CTS types (mg/operator)

	easyconnect						
	Analyte	Range		Arith. Mean	Geo-mean	75th percentile	95th percentile
		Min	Max				
Actual exposure[1]	Sorbitol	0.212	0.155	0.0700	0.0586	0.0858	0.143
	Xylitol	0.186	0.106	0.0346	0.0302	0.0336	0.0768
	easyFlow M						
Actual exposure[1]	Sorbitol	0.0313	0.827	0.170	0.111	0.173	0.482
	Xylitol	0.229	0.0529	0.0365	0.0357	0.0409	0.0492
	GoatThroat® [2]						
Actual exposure[1]	Sorbitol	0.0354	0.259	0.145	0.124	0.200	0.231
	Xylitol	0.0203	0.0461	0.0349	0.0339	0.0419	0.0459

[1] Calculated from the sum of the residues on inner dosimeters, face/neck wipes and hand wash.
[2] Excluding the results from operator 1 who used a different type of probe (telescopic) from the other eleven operators (fixed length).

Fig. 5 Individual operator values for the actual exposure to (a) Sorbitol and (b) Xylitol. Green bars denote easyconnect, blue bars denote easyFlow and orange bars denote GoatThroat®. The red line denotes 10% of the open-pour AOEM 95th centile and the purple line denotes 10% of the open-pour AOEM 75th centile.

Exposure reduction using CTS

Reduction of potential exposure

All three CTS resulted in a marked reduction of the potential operator exposure compared to the AOEM value (Figure 6). The % reduction values for each operator using inverted CTS types for Sorbitol and Xylitol were all above 90% for the 75th and 95th centiles, with the single exception of the 75th centile for Sorbitol for Operator 32 using easyconnect (Figure 6A), for which the reduction was 77% caused by the accidentally higher exposure due to the incorrect use of the connector. Despite this, the overall mean and median % reduction of potential exposure by the inverted CTS forms were 98.8% and 98.7%, respectively (Table 3). While the % reduction values using GoatThroat® for the 95th centile for Sorbitol and Xylitol were mostly above 90% (Figure 6B and D), most of the values for the 75th centile were below 90% (Figure 6A and C), with ranges between 56% and 92% for Sorbitol and 30% and 92% for Xylitol. This resulted in an overall mean and median % reduction of potential exposure by GoatThroat® of 82.5% and 82.0%, respectively (Table 3).

Table 3: Potential exposure reduction of CTS compared to the AOEM for Sorbitol and Xylitol

Mixing and loading — **Sorbitol** exposure/day mixed and loaded [µg] + exposure reduction compared to AOEM (open pouring) [%]										
	75th centile					95th centile				
Matrices	AOEM	inverted systems (easyconnect / easyFlow M)		GoatThroat®		AOEM	inverted systems (easyconnect / easyFlow M)		GoatThroat®	
	[µg]	[µg]	[%]	[µg]	[%]	[µg]	[µg]	[%]	[µg]	[%]
Hands	319513	5217	**98,4%**	107059	**66,5%**	1228313	12419	**99,0%**	180974	**85,3%**
Body	163102	1495	**99,1%**	13391	**91,8%**	349637	9255	**97,4%**	30650	**91,2%**
Head (face/neck wipe)	11933	9,0	**99,9%**	16	**99,9%**	65448	28	**99,96%**	25	**99,96%**
Protected hands (hand washes)	1186	56	**95,3%**	156	**86,8%**	45556	144	**99,7%**	171	**99,6%**
Protected body (inner dosimeter)	2947	65	**97,8%**	65	**97,8%**	33638	98	**99,7%**	97	**99,7%**
Potential Exposure	498682	7637	**98,5%**	118149	**76,3%**	1722592	17421	**99,0%**	210973	**87,8%**
Actual Exposure	16066	130	**99,2%**	200	**98,8%**	144642	199	**99,9%**	231	**99,8%**

Mixing and loading — **Xylitol** exposure/day mixed and loaded [µg] + exposure reduction compared to AOEM (open pouring) [%]										
	75th centile					95th centile				
Matrices	AOEM	inverted systems (easyconnect / easyFlow M)		GoatThroat®		AOEM	inverted systems (easyconnect / easyFlow M)		GoatThroat®	
	[µg]	[µg]	[%]	[µg]	[%]	[µg]	[µg]	[%]	[µg]	[%]
Hands	10285	143	**98,6%**	3840	**62,7%**	38149	312	**99,2%**	8168	**78,6%**
Body	7077	100	**98,6%**	612	**91,4%**	95727	261	**99,7%**	1807	**98,1%**
Head (face/neck wipe)	137	3,0	**97,8%**	2,4	**98,3%**	758	4,0	**99,47%**	5,0	**99,3%**
Protected hands (hand washes)	65	9,0	**86,1%**	13	**80,2%**	527	19	**96,4%**	20	**96,2%**
Protected body (inner dosimeter)	56	31	**45,0%**	24	**56,6%**	389	41	**89,5%**	29	**92,6%**
Potential Exposure	17620	298	**98,3%**	4820	**72,6%**	135551	592	**99,6%**	9180	**93,2%**
Actual Exposure	259	38	**85,3%**	42	**83,8%**	1674	53	**96,8%**	46	**97,3%**

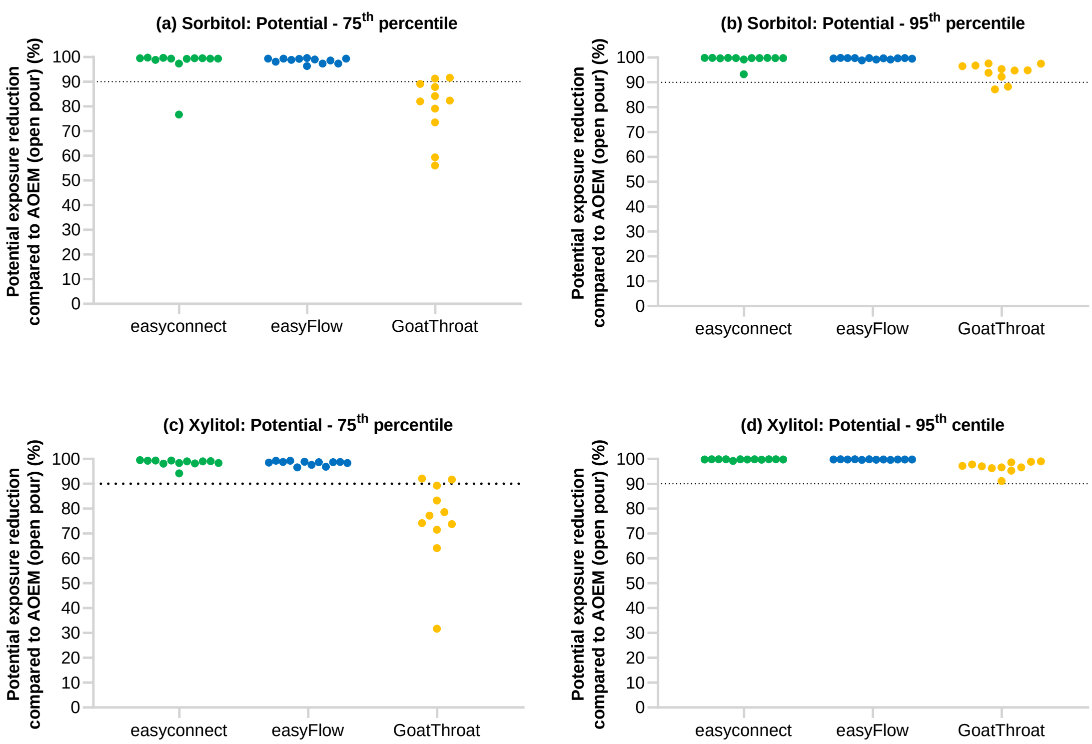

Fig. 6. % Reduction of the 75th and 95th centiles for potential exposure of Sorbitol (a and b) and Xylitol (c and d) to operators using easyconnect (green symbols), easyFlow (blue symbols); GoatThroat® (orange symbols) compared to the AOEM value. The dotted line represents the 90% target reduction.

Reduction of actual exposure

All three CTS forms also markedly reduced actual exposure to Sorbitol and Xylitol (Figure 7). For the high application rate substance, Sorbitol, the % reduction values for the 75% and 95th centiles by all three CTS forms were almost 100% (98.8-99.9%, Figure 7A and B and Table 3). This was also observed for the low application rate substance, Xylitol, for the 95% centile (Figure 7C); however, the values of the % reduction for the 75th centile for Xylitol were lower for both GoatThroat® (83.8%) and inverted CTS (85.3%) (Figure 7C and Table 4). Despite this, the overall mean and median % reduction of potential exposure by inverted CTS types and GoatThroat® were above 94% (Table 4).

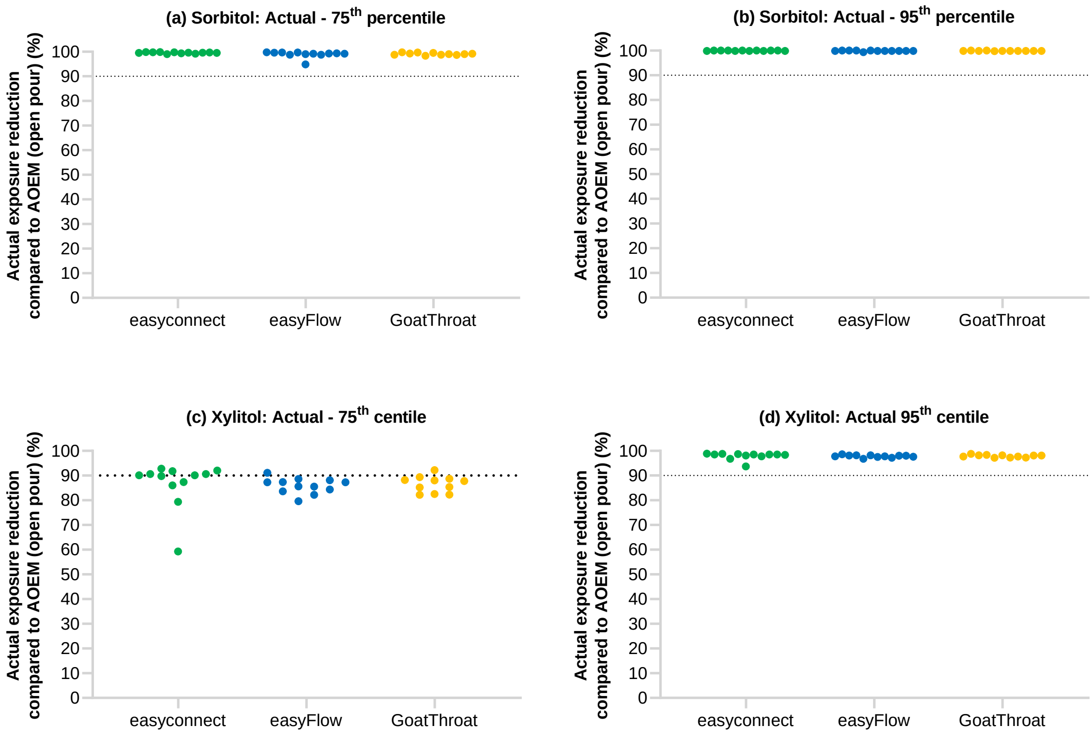

Fig. 7, % Reduction of the 75th and 95th centiles for actual exposure of Sorbitol (a and b) and Xylitol (c and d) to operators using easyconnect (green symbols), easyFlow (blue symbols); GoatThroat® (orange symbols) compared to the AOEM value. The dotted line represents the 90% target reduction.

Table 4. % Reduction of potential and actual exposure using inverted CTS types and GoatThroat®.

		inverted Systems				GoatThroat			
		75th centiles	95th centiles	Mean Value	Median	75th centiles	95th centiles	Mean Value	Median
Potential Exposure	high rate (sorbitol)	98,5%	99,0%	98,8%	98,7%	76,3%	87,8%	82,5%	82,0%
	low rate (xylitol)	98,3%	99,6%			72,6%	93,2%		
Actual Exposure	high rate (sorbitol)	99,2%	99,9%	95,3%	98,0%	98,8%	99,8%	94,9%	98,0%
	low rate (xylitol)	85,3%	96,8%			83,8%	97,3%		

Technical considerations relevant for data interpretation

Classification of CTS types

Since there was no statistical difference between the two inverted CTS models i.e., easyconnect and EasyFlow, with respect to the potential and actual operator exposure, these data can be pooled to represent inverted CTS types when comparing with open-pour exposures.

Potential outliers due to operator error

There was one outlier in the easyconnect dataset. This was due to the operator unintentionally loosening the cap instead of tightening it. This operator error occurred only once during the study and was quickly detected. This operator error can potentially occur with all systems that require rotation of the container along the vertical axis during rinsing. As a result, subsequent training sessions of both systems that require this operation (easyconnect and easyFlow) included advice regarding the connector. By increasing the routine of the operators, this user error disappeared. Despite incident with one operator, the 75th and 95th centile values still resulted in an exposure reduction of >95%.

Cleaning of the containers with GoatThroat® system is performed manually (shaking). The fatigue factor of the operator when manually rinsing 27 containers is important and probably led to reduced diligence by the farmers to properly clean the equipment generating more contamination than is expected when the directions are properly followed.

There was one incident in which the spray tank overflowed during the rinsing of a container with Sorbitol by Operator 15 using easyconnect. The operator immediately stopped his activities and moved away from the affected area. During the overflow, there were no obvious splashes reaching the operator and the spillage was cleaned away by another person. As can be seen in Figures 3 and 5, this did not result in increased exposure to Operator 15.

Exclusion of data from Operator 1

Of note, Operator 1 was excluded from the data evaluation, despite there being no reason to do this from a statistical point of view. Operator 1 used a different probe i.e., a telescope probe, from the other operators using GoatThroat®. A telescope probe has a tube within another, such that the product can be caught between the two tubes, making it difficult to rinse the PPP effectively (especially for viscous liquids). For this reason, the GoatThroat® system with telescopic tube does not pass ISO certification. The use of the telescopic tube by Operator 1 did not result in a markedly higher exposure to Sorbitol but this operator did have highest residue measured for Xylitol. This could be explained by the marked difference in viscosity of both test items. The sorbitol solution with very low viscosity (15 mPas) could be rinsed out between the two overlapping tubes, while the highly viscous (470 mPas) xylitol solution is more difficult to remove.

Recovery rates and background levels

An unexpected finding was that the actual exposures (i.e., the sum of the amount in the inner dosimeter, face wipes and hand wash samples) to Sorbitol and Xylitol did not correlate with the amounts measured on the gloves and outer dosimeters. The values were more reflective of a random spread of amounts present on operators, independent of the CTS type. In theory, neither the hands nor the inner dosimeters should be exposed to the test substances because both are protected by nitrile gloves or the outer dosimeters. However, significant amounts of up to 0.63 mg of Sorbitol and 0.38 mg Xylitol were detected in the hand washes and up to 0.19 mg of Sorbitol and 0.061 mg Xylitol were detected on the inner dosimeters. The reason for random values could be due to Sorbitol and Xylitol being very common sweeteners and the use of these by the operators may have resulted in variable background levels. This may have interfered with the accurate measurement of residues generated during the study, resulting in an overestimation of the amounts in the hand washes and inner dosimeters and an underestimation of the % reduction of actual exposure (which was evident for many values shown in Figure 7C, which were below 90% reduction target). Indeed, in all cases, the residues measured on the protected hands and the inner dosimeters were higher than the unprotected head and neck (the measurements of which ranged between 0.22 and 6.4 µg/person), indicating a certain background level contamination – especially with the inner dosimeters.

For the field recovery and travel fortification samples, the spiked amounts included several which were purposefully very low (e.g., 0.01 and 0.1 µg or µg/L) to ensure that they covered the expected (but at the time unknown) low exposures. However, the background levels of Sorbitol and Xylitol relative to the fortification level significantly interfered with the recovery, therefore, the results for these amounts were unusable. This did not impact the study results because these fortification levels were generally not relevant for the correction of the operator samples. Higher fortification levels generally reflected the residues detected in the operator samples and were thus considered valid (they confirmed the stability of Sorbitol and Xylitol under the environmental conditions during monitoring and during shipment and storage prior to analysis).

Interpretation of results

The use of CTS provides a high level of protection

The study showed that, for the inverted CTS types, there was a reduction of >98% for low and high loading rates for the 75th and 95th centiles for potential and actual exposure. The exception was for the 75th centile for Xylitol for actual exposure, which was considered an underestimation due to the high background levels of this product, which resulted in an overestimation of exposure. The container size was 5 L for the low-rate substance, Xylitol, and 10 L for the high-rate substance, Sorbitol (the latter representing the worst-case scenario). This meant that for each operator, only 3 Xylitol containers were needed compared to 25 Sorbitol containers. Despite the difference in the number of canisters, there was no difference in the extent of protection between the substances. There were also no apparent differences for the loading of small sprayers (more partial dosing required – worst case) and large sprayers. Additionally, not relevant difference could be seen from one country to another.

The use of the GoatThroat® CTS resulted in a significant reduction exposure for the 95th centile, with a reduction in potential and actual exposure of 87% and 99.8% for the high rate and 93% and 97% for the low-rate product, respectively. This CTS also resulted in a significant reduction in potential exposure of >70% with respect to the 75th centile for the low and high-rate product compared to open pouring; however, it did not reach the goal of 90% reduction in exposure. There are several reasons for the lower exposure reduction exhibited by the GoatThroat® compared to that of the inverted CTS. Firstly, GoatThroat® was designed to fill smaller spray rigs with fewer loadings per day than easyconnect and easyFlow (which were specifically designed for transfer of large amounts of PPPs). This introduces a fatigue factor of the operator when manually rinsing 28 containers, which could well lead to reduced diligence by the operators to properly clean the equipment, thus generating more contamination than expected than when the directions are followed properly.

Derivation of reduction factors for exposure calculations when using CTS

The aim of the study was to achieve an exposure reduction of >90% during M&L compared with open-pour data from the AOEM model. CTS types which confirm to the ISO 21191 standards and are shown to reduce exposure by >90% could allow the application of a universal reduction factor as risk mitigation measure when these are used. The use of this reduction factor could be easily implemented in the AOEM calculator. Based on these results, a reduction factor of 0.1 can be applied as a risk mitigation measure.

Conclusions

- All three CTS evaluated in this study were shown to significantly reduce operator exposure to products during M&L.
- Inverted CTS types, easyconnect and easyFlow, resulted in higher mean protection (>98% potential and >95% actual exposure) than GoatThroat® (>80% potential and >95% actual exposure).
- These findings can be used to build confidence of farmers to use CTS routinely, thus resulting in safer pesticide handling.
- These data can be used to derive reduction factors that could be used in the AOEM model for calculations involving mitigation.
- CTS in combination with protective gloves ensures even higher level of protection for any of the systems.

Proposed strategy for calculation of exposure

- All CTS should conform to the ISO 21191 standards to be considered as a mitigation device. This applies to future systems with the same objective (reduce operator exposure).
- All inverted CTS types can be assessed as a single CTS type, whereas probe extraction systems should be assessed separately.
- A reduction factor of 0.05 accounting for mitigation of exposure due to the use of inverted CTS types can be applied when calculating exposure using the AOEM.
- A reduction factor of 0.3 accounting for mitigation of exposure due to the use of probe extraction CTS types can be applied when calculating exposure using the AOEM.